ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 61

[FRL 1259-1]

National Emission Standards for Hazardous Air Pollutants; Policy and Procedures for Identifying, Assessing, and Regulating Airborne Substances Posing a Risk of Cancer

AGENCY: Environmental Protection Agency.

ACTION: Proposed rulemaking.

SUMMARY: This notice proposes for comment a rule governing the policies and procedures to be used by the Environmental Protection Agency in the identification, assessment, and regulation under the Clean Air Act of substances which, when emitted into the ambient air for stationary sources, increase the risk of cancer to the general population. The proposed policy implements for the air program of EPA the principles adopted by the President's Regulatory Council in a statement issued September 28, 1979 on the regulation of chemical carcinogens. In concert with this proposal, EPA is publishing elsewhere in today's Federal Register an advance notice of proposed rulemaking soliciting comments on draft generic work practice and operational standards which could be applied quickly to reduce emissions of airborne carcinogens from certain source categories.

Under the proposed policy, EPA would evaluate available information to identify those substances, including radioactive materials, which should be considered for regulation under the Clean Air Act as airborne carcinogens. Any air pollutant determined to present a significant carcinogenic risk to human health as a result of air emissions from one or more categories of stationary sources would be listed under section 112 as a hazardous air pollutant. Listing under section 112 would be accompanied, where applicable, by the proposal of generic standards for source categories producing or handling significant quantities of the substance. The generic standards would rapidly effect reasonable control of emissions while more detailed analyses are performed to establish priorities for further regulation, determine available control technology, and assess regulatory impacts.

Final standards for source categories presenting significant risks to public health would, as a minimum, require such sources to use best available technology to reduce emissions. If, however, the risk remaining after the application of best available technology is determined to be unreasonable, further control would be required. Unreasonable residual risk determinations would consider the risk remaining, the benefits conferred by the substance or activity, the distribution of those benefits versus the distribution of risks, the availability of substitutes, the costs of further control of the substance or source categories, and proposed sites in the case of new sources. Standards would be reviewed at no more than five-year intervals.

DATES: Written comments should be postmarked no later than February 7, 1980.

Notice of intent to appear at a public hearing should be postmarked no later than November 26, 1979. Hearing dates and locations, which will be held during the comment period, will be announced in the Federal Register.

Written comments responding to, supplementing, or rebutting written or oral comments received at public hearing must be made within 60 days of the hearing date.

ADDRESSES: All written comments should be addressed to: Central Docket Section, Room 2903B, Waterside Mall, 401 M Street, SW., Washington, D.C. 20460, ATTN: *OAQPS 79-14.*

EPA has established a rulemaking docket consistent with procedures established by section 307(d)(1)(N) of the Clean Air Act (42 U.S.C. 7607(d)). The docket number is *OAQPS 79-14* and it already contains the documents on which this proposal is based. All comments received during the comment period, as well as any other documents used in the promulgation of the final rule will be added to the docket promptly. The docket number should be on all written comments. The docket will be open for inspection at the Central Docket section at the above address between 8:00 a.m. and 4 p.m. Monday through Friday.

Notice of intent to appear at a public hearing should be directed to: Joseph Padgett, Director, Strategies and Air Standards Division (MD-12), Environmental Protection Agency, Research Triangle Park, North Carolina 27711.

Additional copies of this notice are available from: Industry Assistance Office, Office of Toxic Substances, U.S. EPA, 401 M Street, SW., Washington, D.C. 20460, 800-424-9065 (toll free) (202) 554-1404.

FOR FURTHER INFORMATION CONTACT: Joseph Padgett, Strategies and Air Standards Division, (919) 541-5204, FTS 629-5204.

SUPPLEMENTARY INFORMATION:

Availability of related information: As described above, documents upon which this proposal is based are available for public inspection in the rulemaking docket (OAQPS 79-14). In addition to these materials, this notice includes a supplemental statement of basis and purpose containing further discussion of the legal basis for the proposed policy, various alternative control strategies considered, and comparisons with other carcinogen policy proposals. This statement follows the text of the proposed rule.

I. Background: The Need for a Policy and a Regulatory Mechanism

A. Introduction

The principal focus of the nation's air pollution control program to date has been the establishment and implementation of standards related to six major pollutant (particulate matter, sulfur oxides, ozone, nitrogen oxides, carbon monoxide, and lead). Recently, increasing attention has been directed towards those toxic components of air pollution which may not be adequately controlled by current programs. Pollutants that may contribute to the occurrence of human cancer have received particular attention because of the nature and seriousness of this group of diseases, and because of recent findings suggesting that a large number of airborne chemicals and radionuclides to which people are exposed may be implicated in cancer and other diseases related to genetic damage. *(1, 2, 3)*

B. The General Cancer Problem

The nature and magnitude of the cancer problem in the United States and the fact that radioactive agents and some chemicals can produce cancer in animals and humans have been well-documented and publicized.[1] Some of the more important aspects of the occurrence and causes of cancer and the role played by air pollution are briefly summarized below.

(1) Nature and Magnitude of the Problem *(4, 5, 6, 7, 8)*

Cancer is a group of diseases characterized by the unrestrained growth of cells that have somehow lost an essential self-regulatory mechanism. The uncontrolled growth of these cells eventually threatens the life of the host organism. Cancer is currently the second

[1] Detailed discussion of the general features of the problem have been presented by the Occupational Safety and Health Administration (*4*), the Consumer Product Safety Commission (*5*), and others (*6*).

leading cause of death in the United States. One American in four is expected to contact some form of cancer in his or her lifetime, and one in five is expected to die from the disease. The most recent statistics show a continued increase in total cancer incidence, due principally to increases in lung cancer.

The social, economic, and human costs of cancer are immense. Most forms of cancer are difficult if not impossbile to cure; less than one-half of all cancer patients live longer than five years from the discovery of their illness. The elusiveness of cures is due largely to the fact that cancer's basic biological mechanisms at the cellular level are not well understood. Approximately 1.8 billion dollars are spent each year for hospital care of cancer patients; significant additional costs not readily estimated include doctor's fees, out-patient therapy, and drug costs. In addition, it is estimated that 1.8 million work-years are lost annually because of cancer.

(2) Causes of Cancer: Importance of Environmental Factors

Studies of human cancer rates, their worldwide geographical variations, and observations of incidence rates in migrant populations have revealed that factors in the human environment are probably responsible for a large proportion of cancers. "Environmental factors" must be understood in the broad sense to include chemical exposures from smoking, diet, occupation, drinking water, and air pollution; various forms of radiation, including sunlight; and some forms of severe physical irritation. Although the uncertainties are great, estimates by the World Health Organization, other prominent institutions, and individual experts have suggested that 60 to 90 percent of all human cancers may be due to these factors. *(37, 9.)*

Studies of cancer incidence in particular groups have shown strong statistical relationships between exposure to certain chemical or radioactive substances and specific cancers. The connection between tobacco smoke and lung and other cancers is the most widely known.*(35)* Significant increases in leukemia and other forms of cancer have been noted among Japanese survivors of atomic bomb explosions during World War II. Markedly elevated cancer rates are found among certain occupational groups in the United States and other highly industrialized countries. In general, cancer rates are higher than average in urban areas.*(10)*

Unequivocal identification and quantification of the specific factors that lead singly or in combination with factors to specific forms of cancer in humans is, however, an extraordinarily difficult task. Observation from human experience is complicated by a number of factors. Purposeful experimentation of humans, for example, is ethically unacceptable, since the result would often be fatal. Definitive epidemiological studies of occupationally exposed groups are often difficult because the relatively small population exposed and inadequate information about duration, magnitude, and circumstances of exposures may not permit statistically reliable conclusions to be drawn. Studies of the cuases of cancer in the general population may be equivocal because of the complex modes of exposure, low exposure levels, and other complicating factors. In addition, synergistic and antagonistic interactions between chemicals substantially complicate any conclusions about the effects of a particular chemical.

Another major difficulty in the interepretation of such studies is the long latency period exposure to carcinogens and onset of the disease. Most cancers observed in today's population probably had their origins in exposures that began 15 to 40 years ago.*(36, 11)* Thus, epidemiological studies in current populations must involve estimation of historical exposures. The latency period also means that epidemiology cannot detect effects of relatively new substances until years of exposure have occurred.

To date, epidemiological studies have identified only 26 environmental agents believed to increase cancer risks in humans. *(12)*. The casual relationships implied by the statistical connections in these studies have generally been supported by controlled experiments on animals. With the possible exceptions of benzene and arsenic, those factors known to produce cancer in humans also produce cancer-in test animals.*(34)* Animal experiments have also implicated many additional chemical substances as potential human carcinogens.

In addition to the potential that a substance acting alone may induce cancer, there is evidence that exposure to certain combinations of carcinogenic and non-carcinogenic agents may promote or potentiate the carcinogenic response. The disproportionate risk of lung caner to cigarette smokers occupationally exposed to asbestos fibers*(36, 37)* is an example of the synergism of two known human carcinogens. Non-carcinogenic and co-carcinogenic substances may also act to promote or enhance the human response to carcinogen exposure.

Although airborne carcinogens may induce cancer at a number of body sites, lung cancer is thought to be the principal form of cancer related to air pollution.*(15)* While cigarette smoking is probably the most important cause of lung cancer in the United States,*(16, 35)* many scientists believe that various air pollutants increase the risk of cancer from smoking and other carcinogenic insults. Available estimates also indicate that occupational exposures are responsible for a significant portion of lung cancer incidence in the United States*(10, 17)*.

Because of the difficulties inherent in studying the causes of cancer and the multifactorial nature of human exposures, the role of each major exposure pathway remains a matter of some debate. While factors such as smoking, occupational exposures, diet, and solar radiation are probably responsible for a greater proportion of cancers than ambient air pollution alone, (*10, 13, 14*) the dimensions of the problem posed by airborne carcinogens remain significant. Besides their contribution to cancers primarily related to other pathways, airborne carcinogens themselves pose risks to large numbers of people. In certain industrialized areas, especially, composite national figures may mask significantly higher air pollution-related cancer risks. And, in the vicinity of specific sources of carcinogenic emissions, risks to individuals can reach very high levels.

A preliminary EPA examination of chemical production, industries producing radioactive materials, and air sampling results has identified over fifty known or potential chemical carcinogens and numerous radioactive materials which may be emitted to the atmosphere. Many of these substances are synthetic organic chemicals that have been in commercial use only since the 1930's. (*18*) Since cancer induced by exposures to small amounts of airbone carcinogens may not appear for 15 to 40 years after exposure, it is still too early to detect the full impacts of these chemicals on human health. Thus, it is both prudent and, in view of the large number of people potentially affected, important to reduce or contain emissions of known or suspected atmospheric carcinogens in order to prevent future problems before they actually are observed.

C. Problems in Regulating Airborne Carcinogens

(1) Introduction

Although significant reductions in emissions of airborne carcinogens have resulted indirectly from control of pollutants such as particulate matter (*19*) and volatile organic chemicals (*20*) under sections 109 and 111 of the Clean Air Act,[2] EPA has taken direct regulatory action to control air carcinogens primarily under section 112.[3] Section 112, National Emission Standards for Hazardous Air Pollutants (NESHAPs), provides for the listing of pollutants which in the judgement of the Administrator cause or contribute to air pollution which may reasonably be anticipated to result in an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness. After a substance is listed as a hazardous air pollutant, EPA must establish control requirements for various source categories which emit the substance. The standards must, in the judgment of the Administrator, provide an ample margin of safety to protect the public health from such hazardous air pollutants. Carcinogens that have been listed under section 112 to date include asbestos, beryllium,[4] vinyl chloride, and benzene. A number of specific emission source categories of these substances have been regulated. (*21, 22*)

A number of scientific, technical, and policy problems have arisen which complicate the regulation of airborne carcinogens under section 112. Significant delays in establishing standards have been associated with determining the appropriate degree of control for certain sources of listed carcinogens. Although the determination of whether and to what degree a particular chemical presents a risk of cancer to humans has not yet been a significant source of delay under section 112, future disagreements are anticipated. This may be particularly true when dealing with substances for which epidemiological data are not available. These problems and their consequences are discussed in the following sections.

[2] 42 U.S.C. Sections 7409 and 7411.

[3] 42 U.S.C. Section 7412. Since the Clean Air Act provides for separate treatment of mobile source emissions under Title II, this policy addresses only air emissions from stationary sources. At this time, carcinogenic emissions from stationary sources appear to present a larger and more diverse public health problem than mobile source emissions.

[4] Beryllium was listed because of its non-carcinogenic toxic properties.

(2) Difficulty in Determining Carcinogenicity

The carcinogenic substances listed under section 112 to date were recognized as human carcinogens on the basis of epidemiological evidence. For most other chemical substances, however, such evidence will not be available, and other means of assessing carcinogenicity will have to be employed.

Protection of public health from current and future cancer risks therefore requires reliance on the results of laboratory tests, primarily involving animals, in the identification of probable human carcinogens. Practical limitations require that most animal tests be conducted with much smaller numbers of subjects than the human populations they represent, and at doses much higher than ambient exposure levels to improve the detectability of carcinogenic effects.

Evaluation of the carcinogenic risk to humans, based on such animal tests of candidate substances, raises a number of issues. Among these are the differences between species, extrapolation from the high doses administered to animals to the low concentrations present in the ambient air, differences in routes of exposure (e.g., ingestion versus inhalation), the significance of benign tumors, and the question of no-effect "thresholds" at lower exposures. Since animal testing is of key importance in carcinogen identification, policy decisions must be made and articulated on each of these issues.

(3) Problems Associated With the Large Number of Potential Air Carcinogens and Sources

Further difficulties in dealing with air pollution-related cancer result from the large number of potential atmospheric carcinogens and the correspondingly large number of sources emitting them. Preliminary analyses have identified a number of source types which may emit carcinogenic substances to the atmosphere. Most of these types fall into one of the following six broad groups: (1) mining, smelting, refining, manufacture and end-use of minerals and other inorganic chemicals; (2) combustion; (3) petroleum refining, distribution, and storage; (4) synthetic organic chemical industries and end-use applications, and waste disposal; (5) mining, processing, use, and disposal of radioactive substances and radioactive by-products; and (6) non-carcinogenic emissions which are chemically transformed into carcinogens in the atmosphere.

A survey of several thousand potential toxicants emitted from one broad category, the synthetic organic chemical industry, has identified over six hundred organic chemicals of possible concern. (*18*) Of these, over 140 showed some indication of possible carcinogenicity, mutagenicity, or teratogenicity. The results of a preliminary analysis of these substances suggest that as many as 40 of these substances are of concern as potential air carcinogens. (*29*) Although the synthetic organic chemical industry comprises the largest source grouping, a number of additional organic and inorganic air pollutants of concern, and a number of radioactive materials, are emitted from the other source categories.

Currently, EPA has only limited information on the emission rates, sources, and atmospheric concentrations of most potential airborne carcinogens. As a result of the generally low ambient concentrations expected from emissions of many of these substances, as well as their large number, source emissions testing and atmospheric monitoring programs will be more sophisticated and expensive, but less accurate or precise, then traditional air pollution monitoring. The resources necessary for developing such programs and for evaluating the health effects and control alternatives for this large number of substances and sources far exceed those currently available to EPA for the task. Clearly, priorities must therefore be established to maximize the public health benefits obtainable with existing resources.

(4) Difficulty in Determining the Appropriate Degree of Control

As noted above, a central problem in establishing standards and reqirements for air carcinogens under section 112 of the Clean Air Act has been determining the appropriate degree of control which should be required for significant source categories. The difficulty is related both to the characteristics of carcinogens and to the requirement of section 112 that the public health be protected with "an ample margin of safety."

As discussed above, most identifications of substances as probable human carcinogens have been based on studies of humans or animals exposed to relatively high doses of the substances. Whether the smaller doses generally encountered in the ambient environment cause cancer or, whether instead, some threshold or "safe" level of exposure may exist is a matter of considerable scientific debate. (*23*) EPA and other public health agencies and groups have, as a matter of prudent health policy, taken the position that in

the absence of identifiable effect thresholds, carcinogens pose some risk of cancer at any exposure level above zero. The existence of risk at any exposure level has created difficulty in setting required control levels. Some commenters have maintained that no risks should be permitted from emissions of carcinogens, while others argue that, in view of the uncertainty that any effect will occur at low exposure levels, only feasible and clearly cost-effective controls should be required.

This difficulty has been compounded by the language of section 112 itself, which calls for the establishment of standards which, in the judgment of the Administrator, provide "an ample margin of safety to protect the public health" from hazardous air pollutants. This language clearly mandates that the primary factor in standard-setting under section 112, in contrast to some other sections of the Act, such as section 111, be the protection of public health. How this mandate should be translated into standards for airborne carcinogens, however, is not clear. This uncertainty has led to delay and litigation, with some arguing that the *only* factor that may be considered is health effects, while others contend that EPA should simply balance risk against the cost of control and the benefits of the activity, giving all factors equal weight. While EPA has made limited statements (*21, 22*) of its view of section 112, the Administrator has not expressed a comprehensive interpretation of the provision as it applies to the regulation of carcinogens until now.

(5) EDF Petition

Citing concerns over the limited number of carcinogens listed as hazardous air pollutants to date and the regulatory delays encountered in controlling vinyl chloride, the Environmental Defense Fund (EDF), in November 1977, petitioned EPA to adopt a generic approach for classifying and regulating carcinogenic air pollutants under the Clean Air Act *(30)*.

The EDF proposal is patterned on the classification system proposed by OSHA and is based on scientific criteria similar to those articulated by CPSC, OSHA, and EPA for carcinogenicity determinations.[5] Suspect substances would be grouped into three categories (confirmed, probable, possible) based on the availability evidence of carcinogenicity. Under the main feature of the policy suggested by EDF, a determination that an air pollutant is a confirmed carcinogen would trigger the following responses: (a) immediate listing as a hazardous air pollutant under section 112; and (b) proposal and promulgation of regulations to (1) either ban the use of the material if a suitable substitute exists, or to require the application of emissions or equipment standards representing best available control technology; (2) establish a timetable leading to the reduction of emissions to zero at both existing and new sources; and (3) prevent any increase in emissions from additions to or replacements of existing facilities.

In March 1978, EPA conducted a public meeting to receive comments on the EDF proposal and any other suggestions regarding the Agency's regulatory process for the control of airborne carcinogens *(31, 32)* [6]. One major presentation made at that meeting was by the American Industrial Health Council (AIHC), advocating the use of a central board of non-governmental scientists for evaluating carcinogenicity and carcinogenic potency of substances of interest for all federal regulatory agencies *(33)*. The principles AIHC recommended for determination of carcinogenicity differ somewhat from those proposed by EPA, CPSC, and OSHA. AIHC also recommended that standards be set independently for each substance through a process of "balancing" predicted cancer incidence, costs of control, and benefit of the substance regulated. While AIHC gave examples of alternative balancing procudures which might be used, it did not recommed any specific course of action to EPA for use under section 112.

(6) Need for an Air Carcinogen Policy

The problems associated with the determination of carcinogenicity, the large number of potential carcinogens, and the appropriate level of control of emitting sources contribute to delays in decisions to list carcinogenic substances as hazardous air pollutants as well as to delays in establishing control requirements under section 112. Indeed, EPA has listed only three air pollutants as carcinogens under section 112 since 1970. Therefore, given the potentially large number of airborne carcinogens which may require control, the general unavailability of epidemiological data for determining carcinogenicity and potential risks, the requirements of section 112, and EPA's experience under section 112 to date, the Administrator has concluded that the establishment of a comprehensive and coherent policy and set of procedures for regulatory action in dealing with airborne carcinogens is imperative.

Specifically, publicly-stated, legally binding policies and regulatory mechanisms are needed for: (1) determining the carcinogenicity and carcinogenic risks of air pollutants for regulatory purposes; (2) establishing priorities for evaluating the need for and accomplishing additional regulatory action; (3) specifying the degree of control required in general under section 112 and how that level of control will be determined in setting individual standards; and (4) providing more extensive public involvement in the Agency's decisionmaking on the regulation of airborne carcinogens. Among the benefits of adopting such a policy, in addition to more expeditious control of probable carcinogens, are increased public understanding of and participation in EPA's actions and the providing of earlier notice of EPA's findings and intent to state and local regulatory authorities and to industries.

II. Discussion of the Proposed Rule

A. Introduction

The provisions of the proposed rule are stated formally at the end of this notice. The following sections present the Agency's rationale for, and describe the operation of, the proposed policy. Certain related issues, including the detailed legal basis of the proposal, the consideration of various alternatives, and a comparison with other policies, are discussed in a supplemental statement of basis and purpose following the text of the proposed rule. The Administrator intends to publish a finding at the time of the promulgation of this rule stating that the rule is based on determinations of nationwide scope and effect. The provisions of section 307(b) of the Act, 42 U.S.C. section 7607(b), will therefore limit judicial review to the U.S. Court of Appeals for the District of Columbia Circuit, and litigation of the issues posed by this rule will not be available in connection with subsequent rulemakings in which it is applied.

Pending final promulgation of the rule, as it may be modified after public comment, EPA will generally follow the proposed policy and procedures in actions taken in the interim. Such actions are expected to be listing decisions or regulatory proposals for specific substances, so that EPA will be able to reflect, in final regulatory action on such substances, any changes made in the proposed rule after public comment.

[5] A comparison of these approaches is presented in the supplemental statement which follows the text of the proposed rule.

[6] The comments received at that meeting have been considered in the formulation of today's proposal.

B. Identification and Preliminary Evaluation of Health Risks

This section describes the principles and procedures that EPA will use in identifying potential airborne carcinogens and in determining whether emissions of such substances pose significant risks to public health. These principles and procedures address determinations in three fundamental areas: (1) the generic determination that the presence of airborne carcinogens in relatively low ambient concentrations warrants regulatory action, (2) the identification of specific candidate substances for EPA assessment, and (3) the assessment of whether such substances pose significant risks to public health.

(1) The Need for Concern About Relatively Low Doses

The Administrator's belief that ambient concentrations of carcinogens represent a significant public health risk warranting regulatory action is based on the current understanding of the biological effects of these substances at low concentrations. Essentially, two hypotheses exist. The non-threshold hypothesis assumes that cancer can result from the interaction of as little as one molecule of a carcinogen with a critical receptor in one cell.

The threshold hypothesis, in contrast, assumes that there is a no-effect dose of a carcinogen below which induction of cancer cannot occur. This hypothesis argues that, at small doses, chemical carcinogens can be detoxified through metabolic processes, resulting in some level of exposure which produces no carcinogenic response, or that repair mechanisms or cell death may prevent the development of cancer from a single damaged cell.*(23)*

The public health community has generally concluded that evidence for identifiable dose thresholds does not exist for carcinogens. Under this view, any exposure to a carcinogenic substance carries a risk of cancer. A recent report by the National Academy of Sciences*(24)* offers the following observations in support of this conclusion:

> Consideration of the Dose-Response Relationship. In considering the possibility of thresholds for carcinogenesis, it is important to understand that there is no agent, chemical, or physical, which induces in man a form of cancer that does not occur in the absence of that agent. In other words, *when there is exposure to a material, we are not starting at an origin of zero cancers. Nor are we starting at an origin of zero carcinogenic agents in our environment. Thus, it is likely that any carcinogenic agent added to the environment will act by a particular mechanism on a particular cell population that is already being acted on by the same mechanism to induce cancers.* This reasoning implies that the only way for a new carcinogen added to the environment to have a threshold in its dose-response curve would be if it were acting by a mechanism entirely different from that already being experienced by that tissue.
>
> Examination of Experimental Dose-Response Curves. The most extensive information on carcinogenesis both in experimental animals and in humans is with ionizing radiation. Although there is evidence implicating thresholds in some animal tissues, thresholds have in general not been established for most tissues. If such thresholds exist, they occur at sufficiently low doses that it would require massive, expensive, and impracticable experiments to establish them. In view of the common finding—for example, a linear dose-response relationship (unaffected by dose-rate)—of cancer induction in animals by high LET [Linear Energy Transfer] radiation, it is unlikely that such thresholds exist. Linearity is not essential to the no-threshold argument since nonlinear, dose-response relationships do not necessarily imply the existence of thresholds . . .
>
> Heterogeneity of the Population. The human population in the United States—the population we are trying to protect—is a large, diverse, and genetically heterogeneous group exposed to a variety of toxic agents. Genetic variability to carcinogenesis is well-documented (Strong, 1976), and it is also known that individuals who are deficient in immunological competence (for genetic or environmental reasons) are particularly susceptiple to some forms of cancer (Cottier, et al., 1974).
>
> It seems, therefore, that even if we were to postulate an average threshold for a particular cancer induced by a particular agent, we would in practice need a series of thresholds for different individuals. It would be extremely difficult, in practice, to establish a single threshold.
>
> We conclude from these arguments that, despite all the complexities of chemical carcinogenesis, thresholds in the dose-response relationships do not appear to exist for direct-acting carcinogens. If they do exist, they are unlikely to be detected and, hence, impossible to use. This means that there can be no totally "safe" exposure to a particular carcinogen. (Emphasis added.)

EPA has therefore made a generic determination that, in view of the existing state of scientific knowledge, prudent public health policy requires that carcinogens be considered for regulatory purposes to pose some finite risk of cancer at any exposure level above zero. The Administrator believes that this is consistent with the mandate of section 112 requiring the protection of public health against air pollutants which "may reasonably be anticipated" to cause or contribute to the health effects of concern, and the application of an "ample margin of safety" in making such public health judgments.

(2) Identification and Screening of Potential Airborne Carcinogens

Potential airborne carcinogens are now and will continue to be identified through various EPA programs, including searches of the scientific literature, monitoring studies, and biological assays of substances found in ambient air and source emissions, as well as by examining information obtained from federal, state, or other regulatory authorities, private research groups, and other scientific sources. Suspect substances (compounds or mixtures) identified in this manner will be screened to provide a rough estimate of the potential extent of public exposure resulting from ambient air emissions. Screening is essential for two reasons: first, to optimize the use of Agency resources in view of the growing number of substances of concern, and second, to distinguish between those substances which may, through their presence in the air, present carcinogenic risks and those which, although probably carcinogenic, are not emitted in quantities sufficient to pose such risks.

Readily available information will be collected on the intentional and inadvertent production of such substances and their uses, volatility, and other chemical and physical properties. Ambient air measurements and previous scientific assessments will be considered where available. Appropriate offices within EPA and other relevant agencies will be contacted to determine whether any regulatory actions, assessments, or screening activities are underway.

Suspect substances to which the screening process indicates the public is probably exposed through ambient air will receive further attention to evaluate the likelihood that they pose significant carcinogenic risks. Priorities for these evaluations will be assigned based on the expected potential for public exposure to the substances. In some cases, EPA may determine after screening that regulatory actions under other laws administered by EPA or by other regulatory agencies eliminate the need for further EPA action under the Clean Air Act. Otherwise, potential airborne carcinogens will be evaluated for the likelihood that they pose significant risks to public health.

These procedures are already in operation. As noted above, screening of over 140 potential airborne carcinogens has yielded of 40 for which carcinogenicity determinations and preliminary exposure assessments are underway. These determinations are

excepted to be largely completed by December 1979.

(3) Evaluation of Significance of Risk to Public Health[7]

The determination of significant carcinogenic risk will be based on assessments in two areas: the probability that the substance is a human carcinogen, and the extent of human exposure via the ambient air.

(a) *Evaluation of the Probability of Human Carcinogenicity.* The criteria for evaluating the probability that an airborne substance presents a carcinogenic risk to humans are not unique to the air, but are conceptually the same as those for substances present in any exposure medium. It would thus be inappropriate for EPA to use a novel set of criteria for airborne substances alone. Accordingly, in determining the carcinogenic risk posed by air pollutants, EPA will use the criteria specified in general guidelines adopted by the Agency. The EPA "Interim Guidelines for Carcinogen Risk Assessment" ("Interim Guideline") issued on May 25, 1976 *(25)* outlines the basic scientific criteria and policy judgments currently used by EPA in evaluating evidence regarding suspect carcinogens. This guidance is supplemented by the recent release for comment by the Risk Assessment Work Group of the Interagency Regulatory Liaison Group (IRLG)[8] of a scientific review of the principles and methods applicable to the identification and assessment of human risk from carcinogens. *(26)*

In evaluating the likelihood that a substance is carcinogenic in humans under EPA's Interim Guideline and the IRLG Work Group report, available information is considered and judgments concerning the probability of human carcinogenicity are made based on the quality and weight of evidence. The information principally relevant to such an evaluation includes epidemiological and animal or other laboratory studies.

The available information is evaluated in light of the following criteria:

Judgments about the weight of evidence involve considerations of the quality and adequacy of the data and the kinds of responses induced by the suspect carcinogen. The *best evidence* that an agent is a human carcinogen comes from epidemiological studies in conjunction with confirmatory animal tests. *Substantial evidence* is provided by animal tests that demonstrate the induction of malignant tumors in one or more species including benign tumors that are generally recognized as early stages of malinancies. *Suggestive evidence* includes the induction of only those non-life-shorting benign tumors which are generally accepted as not progressing to malignancy and indirect tests of tumorigenic activity, such as mutagenicity, *in vitro* cell transformation, and initiation-promotion skin tests in mice. *Ancillary* reasons that bear on judgments about carcinogenic potential, e.g., evidence from systematic studies that relate chemical structure to carcinogenicity, should be included in the assessment. *(25)*

This "weight of evidence" evaluation outlined in the Interim Guideline does not involve automatic categorization of carcinogenic probability, but rather evaluates the nature of the evidence in each case. Once the evidence has been weighted, of course, the conclusions must be useful for regulatory decisions. For this reason, substances which have been evaluated will be grouped into three broad categories (high, moderate, low) according to the probability of carcinogenicity. Assignment to a particular regulatory category will be made on a case-by-case basis, and will reflect the strength of the evidence that the substance in question is a human carcinogen in comparison with the range of other substances which have been evaluated for regulatory action. In general, substances for which "best" or "substantial evidence" as described above exists will be considered for designation as high-probability human carcinogens for purposes of section 112. Substances for which only "suggestive" evidence exists will be considered for designation as moderate-probability human carcinogens. Substances for which only "ancillary" evidence exists will be considered for designation as low-probability human carcinogens.

EPA recognizes that a range of scientific uncertainty exists within these broad evidentiary classes. For example, a substance which has been found to be carcinogenic in all animal species and sexes tested may be more likely to be carcinogenic in humans than a substance tested in several species and found to produce tumors in only one sex of one species. Although upon consideration of the relative strength of evidence it may be concluded that both substances should be considered high-probability human carcinogens, the extent of uncertainty will be considered on a case-by-case basis.

(b) *Preliminary Evaluation of Ambient Exposure.* EPA will also determine whether a suspect airborne carcinogen is emitted into or present in the ambient air in such a way that significant human exposure results. While the threshold of significance for the ambient exposure determination will be relatively low, some consideration of exposure levels is appropriate to avoid initiating regulatory action under the Clean Air Act for substances such as "laboratory curiosities" which are very unlikely to be present in the ambient air in measureable quantities. This preliminary exposure evaluation is designed to make that distinction.

In the preliminary assessment of ambient exposure, EPA will consider available data on ambient concentrations of the substance, the number and nature of emitting sources, and the number of people living near the sources or in areas in which ambient concentrations have been reported. Where possible, preliminary estimates of lifetime individual risks to the potentially most exposed individuals, based on estimates of carcinogenic strength, will also be calculated.

The preliminary exposure assessment will not be designed to produce the more detailed information appropriate in deciding what control measures may be necessary; that information, including detailed quantitative assessments of risk, will also be developed where possible by EPA, but is not required for the determination of significant ambient exposure.

C. Initial Responses to Preliminary Assessments of Health Risks

The evaluation of the significance of risk to public health will be used to identify those substances for which, in the judgment of the Administrator, there is sufficient evidence to warrant listing under section 112 as airborne carcinogens. For substances which fall short of meeting the criteria for this determination, or for which available information is not sufficient to make a determination, the proposed policy provides for alternative responses. The following paragraphs describe EPA's specific responses to various possible evaluations under the proposed rule.

(1) Listing Under Section 112: Significant Risk

Any subtance judged by the Administrator to present significant carcinogenic risks to the public will be

[7] Today's notice deals only with the carcinogenic hazards of an air pollutant. A substance may also be regulated under section 112 due to its non-carcinogenic health effects, or due to a combination of carcinogenic and other serious effects. Non-carcinogenic effects of substances being reviewed as possible airborne carcinogens will also be evaluated and considered where information on those effects is available.

[8] IRLG Agencies include Environmental Protection Agency, Occupational Safety and Health Administration, Consumer Product Safety Commission, Food and Drug Administration, and Foods Safety and Quality Service (U.S. Department of Agriculture). The Occupational Safety and Health Administration, however, did not participate in the joint issuance of the Risk Assessment Work Group report.

listed under section 112 as a hazardous air pollutant. The finding of significant carcinogenic risk is based on the judgment that a substance has a high probability of human carcinogenicity, and evidence of significant public exposure via the ambient air from emissions from one or more categories of stationary sources.

A high-probability carcinogen may also be listed under section 112 if a preliminary quantitative risk assessment suggests that there is a significant risk to the potentially most exposed groups as a result of emissions of the substance. These preliminary assessments of risk will be considered as supplemental evidence that listing is warranted where the available evidence before the Administrator is otherwise insufficient to indicate the existence of a significant risk. In the judgment of the Administrator, it would not be prudent health policy to base a decision not to list upon a preliminary risk estimate in the presence of qualitative evidence of significant human exposure.

The limitation of the role of these preliminary risk assessments to supplementary evidence in support of a finding of significant risk is based on the Administrator's judgment that these quantitative estimates are too imprecise and uncertain to use as a factor in deciding *not* to list a substance. The Administrator does believe, however, that despite their considerable uncertainty it would be imprudent to ignore assessments suggesting the existence of significant risk, especially in light of the limited direct consequences of listing. The Administrator's views concerning the use of quantitative risk assessment under this proposal are discussed in greater detail elsewhere in this notice.

The timing of the listing decision for a given airborne carcinogen will depend on the nature of the information available to the Administrator. Initially available information will often be adequate to conclude that emissions of the sustance present a significant risk to the public. If so, listing would occur immediately upon that finding. Sometimes, however, the preliminary assessments will not provide enough information to allow the Administrator to decide if emissions of a substance present a significant risk. Where that is the case, further information will be obtained to allow a determination to be made. Substances for which exposures are potentially substantial will be assigned high priority for this further effort.

The purposes of this "early" listing approach are: to increase the priority of a substance for further action, to facilitate the expeditious application of clearly necessary control measures to certain sources, to accelerate the process by which final regulatory decisions are made, and to provide for earlier public notice of the Agency's views and increased public participation in the regulatory decision-making process. Paragraphs (a) and (b) below describe the immediate consequences of listing under the proposed policy.

(a) *Listing Where Generic Standards Are Applicable.* As explained more fully in a companion advance notice of proposed rulemaking (ANPR) elsewhere in today's Federal Register, EPA has developed a draft set of low-cost and readily implemented control procedures and work practices that can be applied to control emissions from various categories of sources producing, consuming, and handling significant quantities of a broad class of substances (volatile organic chemicals) sharing certain properties. Where substances listed as carcinogens under section 112 are emitted from source categories to which these "generic standards" could apply, the application of the standards would be proposed immediately upon listing.

The draft generic standards published elsewhere in the notice as an Advance Notice of Proposed Rulemaking (ANPR) were developed from information and efforts of EPA's Synthetic Organic Chemical Manufacturing Industry (SOCMI) standards development program. This program was initiated in 1976 to gather technical and cost data on the control of air pollution from organic chemical manufacturing and to prepare (1) new source performance standards (NSPS) for total volatile organic compound (VOC) emissions, (2) control techniques guidelines (CTG) for VOC emissions, and (3) section 112 standards for specific volatile organic chemical emissions.

The SOCMI program has focused its efforts on four kinds of emissions: (1) emissions from storage tanks and transportation vessels, (2) fugitive leaks and spills of VOC, (3) losses of VOC from liquid and solid wastes, and (4) emissions from process vents. Information-gathering, analysis, and standards development are at various stages in these four areas, and the program's goal is to develop generic standards in each area. The draft generic standards in today's ANPR, dealing with leaks and spills of VOC, represents the first generic application of information developed by the SOCMI program to standards under section 112. As further information becomes available from the program relating to the other kinds of emissions under study, EPA intends to develop further generic standards for use in conjunction with section 112. EPA would expect to follow a public paritipation and regulatory development process similar to that of today's ANPR in connection with the development of additional generic standards.

The draft generic standards which are contained in today's ANPR would apply to a large proportion of the organic chemical industry, and are based on the similarity of many operations and equipment throughout the industry. Examples of required procedures are the periodic inspection for and reporting of fugitive leaks and subsequent repair, and the painting of storage tanks white to reduce volatilization of organics. Since most of the potientially carcinogenic chemical air pollutants identified by preliminary surveys to date have been organic chemicals, these generic standards would be expected to apply to the significant sources of most of the chemical carcinogens which might be listed.

In general, the applicablility of the draft generic standards would be dependent on the characteristics of source operations and the quantity of the substance which is produced or handled. The application of the draft generic standards would be proposed only for sources dealing with significant quantities of the listed substance, and some "tailoring" of the standards may be necessary for source categories of each listed pollutant. Sources currently meeting the requirements of such standards would effectively be required to continue doing so. The purpose of the immediate proposal of the generic standards is to ensure that risk reduction which can quickly and easily be achieved through the implementation of clearly appropriate "good housekeeping" measures is not delayed by the further assessments and detailed analyses which will be conducted before final regulatory decisions are made.

These initial regulatory requirements would not be applicable to all airborne carcinogens, and would not necessarily represent the degree of control which may ultimately be required. Because the draft generic standards currently address only fugitive emission sources, further standards will have to be developed individually to control process emissions from significant source categories. As further generic standards are developed for the remaining types of emission points and processes, the extent to which further control requirements will have to be

developed and applied on a case-by-case basis will decrease significantly.

(b) *Listing Where Generic Standards Are Not Applicable* While a substantial majority of the substances which will be listed under section 112 as airborne carcinogens are expected to be chemicals to which generic standards could apply, there will be other substances such as inorganics or radioactive materials emitted from source categories for which generic standards have not been developed. In these cases, listing of a substance will trigger the assignment of a priority for the development of final emission regulations for significant categories of sources emitting the substance.

(2) Regulation Under Section 111: Moderate Probability of Carcinogenicity and High Exposures

Substances for which the probability of human carcinogenicity is moderate to low generally will not be considered for immediate regulation as carcinogens under section 112. If analysis suggests high exposures to a substance of "moderate probability," however, the resulting risk of cancer to the general population remains of concern. Such a substance will therefore undergo further assessment and, unless that assessmet indicates the substance is a high-probability carcinogen, will be considered for interim regulation under section 111 of the Clean Air Act.

Under section 111, new and existing sources may be regulated if they cause or contribute to "air pollution which may reasonably be anticipated to endanger public health or welfare." While a substance of only moderate probability of carcinogenicity would not generally "be reasonably anticipated to result in an increase in mortality or an increase in serious irreversible or incapacitating reversible illness," high exposures to that substance certainly may *endanger* public health. Such a substance may therefore be regulated under section 111.

(3) Further Assessment or Testing

EPA will conduct, recommend, or request that others conduct further biological testing on low or moderate probability substances. Testing may include both cancer and other toxicity assays with priorities based on the extend of public exposures.

(4) Quantitative Risk Assessments for Listed Carcinogens

EPA will conduct a quantitative risk assessment, if possible, for any substance which has been listed under section 112 as a carcinogen. While such quantitative assessments are subject to considerable uncertainty, the Administrator believes that they can provide useful information for two phases of the proposed policy: establishing priorities for regulation of specific source categories of listed pollutants, and determining the degree of control required in final emission standards for those source categories. In assigning priorities for risk assessments, consideration will be given to the likelihood of significant exposures, the effect of any generic standards proposed, carcinogenic strength (potency), and the feasibility of expeditious control.

(a) *Nature of Quantitative Risk Assessments.* Quantitative risk estimates at ambient concentrations involve an analysis of the effects of the substance in high-dose epidemiological or animal studies, and extrapolation of these high-dose results to relevant human exposure routes at low doses. The mathematical models used for such extrapolations are based on observed dose-response relationships for carcinogens and assumptions about such relationships as the dose approaches very low levels or zero. *(23), (25), (26)* Examples of such models are the linear non-threshold model and the log probit model. *(25)* Often, assumptions must be made regarding the relevance of studies involving doses given through feeding or other pathways in extrapolating to inhalation exposures. Where only animal studies exist, additional assumptions must be made concerning "mouse to man" extrapolations.

The risks to public health from emissions of a high-probability carcinogen may be estimated by combining the dose-response relationship obtained from this carcinogenicity strength calculation with an analysis of the extent of population exposure to the substance through the ambient air. Exposure in this context is a function of both the concentraton of a substance and the length of time the concentration is encountered. A detailed exposure analysis will estimate likely exposures for long-term temporal trends, short-term maximum levels, and weighted averages for both the total population exposed and subgroups whose exposures may be significantly greater or otherwise different from the average.

Although ambient monitoring data will be used whenever possible, exposure analyses will often be based on the use of air quality models, available estimates of emissions from significant source categories, and approximations of population distributions near the source categories. Similar models may be used to estimate exposure through other pathways ultimately resulting from air emissions. Detailed air quality models will be used to estimate the range of pollutant exposures associated with each major source category. The air quality models used will generally permit estimation of exposures of up to 20 kilometers and and in some cases 80 kilometers from individual sources. Population and growth statistics will be examined to allow projections to be made of future exposures. The information collected, tegether with the existing carcinogenic strength determinations, will be used to provide estimates of the degree of risk to individuals and the range of increased cancer incidence expected from ambient air exposures associated with source categories of the carcinogenic air pollutant at various possible emissions levels.

(b) *Uncertainties in the assessment of Risk.* The assumptions and procedures discussed above for extrapolation and for exposure estimates are subject to considerable uncertainty. Where only animal data are available to assess the magnitude of cancer risk to human populations, the differences in susceptibility between animal species and humans, and the need to extrapolate dose-response data to very low ambient concentrations, result in risk estimates that must be regarded only as rough indications of effect. *(25)*

Uncertainty in exposure estimates arises from the use of limited monitoring, pollutant transport models, mobility of the exposed population and other factors. In combining these exposure estimates with dose-response extrapolations to provide estimates of cancer incidence, the total uncertainties are increased.

The primary model that EPA will use to estimate carcinogenic risk from exposure to a particular substance will be the linear non-threshold dose/response model. This model has been chosen in order to avoid understating the risk calculated from the extrapolation of the effects osbserved at high doses to the lower doses characteristic of ambient exposure. To the extent possible, the range of uncertainty in the risks extrapolated from animal studies to humans and from high to low doses will be described.

The decision to employ estimates of carcinogic risks despite their lack of precision rests on the belief that although they are subject to considerable uncertainties, current analytical models and techniques can, with due consideration of the uncertainties, provide useful estimates of relative carcinogenic strength and of

the probable general ranges of excess cancer incidence and individual risks. This view has been supported by the National Academy of Sciences, *(24)* the National Cancer Advisory Board, *(27)* and others. *(28)*

D. Establishment and Review of Emission Standards and Related Requirements

(1) Introduction

A central issue in developing a policy for the protection of public health from carcinogens is the determination of the extent to which exposures must be reduced. Given the impossibility of identifying levels of carcinogens with no associated risk, some have argued that no exposure should be tolerated and that emissions should be reduced as expeditiously as practicable to zero. Others contend that permissible exposures should be determined by an unstructured balancing of risks, costs, and benefits.

A number of approaches for addressing the appropriate level for control of carcinogens have been considered or proposed by the federal regulatory agencies, industrial groups, environmental organizations, and others. Prominent examples include the OSHA proposal, the CPSC policy,[9] and the EDF petition on airborne carcinogens. A discussion of the suggested alternatives is presented in the supplemental statement which follows the text of the proposed rule. The following sections describe the approach proposed by EPA.

(2) The Proposed EPA Approach

The standard-setting policy proposed today requires, as a minimum, the use of "best available technology" (BAT) to control emissions from source categories presenting significant risks to public health. The policy would also require additional controls, as necessary, to eliminate "unreasonable residual risks" remaining after the use of best available technology. This approach is a judgmental one, designed to protect the public health with an ample margin of safety from risks associated with exposure to airborne carcinogens. The implementing procedure described below puts prime emphasis on public health, consistent with section 112, but permits consideration of economic impacts and benefits of the activity in setting standards for each source category. Uncertainties in the assessments of risks, costs, and potential benefits, as well as the distributional (equity) problems of various situations, would also be considered in setting standards.

(a) *Source Categories Regulated*

The first step in establishing standards and requirements for pollutants listed under section 112 under this proposed policy is the determination of which categories of sources emitting the pollutants will be regulated, and in what order regulations will be developed. Although a pollutant may have been listed because emissions from a particular source category pose a significant risk, other source categories may also emit the pollutant in lesser amounts. This may occur, for example, because the sources process very little of the substance, because the substance is present in only trace amounts in the sources' raw materials, or because sources have installed adequate controls on their own initiative or in response to other regulatory requirements.

The Administrator will therefore propose regulations only for those source categories which may pose significant risks to public health. The determination of whether a source category emitting a listed pollutant poses a significant risk will be made on essentially the same basis as the listing decision, except that the more detailed exposure analysis and risk assessement then available will be used in lieu of the preliminary information used in the listing decision. As in the listing decision, the risk assessment will be used to indicate the existence of a significant risk where the exposure analysis alone is insufficient, but will not be used as evidence that a significant risk does not exist where the exposure analysis indicates to the contrary.

(b) *Priorities for Development of Standards.* EPA anticipates that a substantial number of substances will be listed as carcinogenic air pollutants under section 112 in the near future. It is also likely that many of these substances will be emitted in significant quantities from more than one source category. As a result, EPA will need to develop emission standards and other requirements for a large number of source categories emitting these substances. At least until generic standards can be developed for large groups of these sources, the resources that would be necessary to complete this task immediately far exceed those available to EPA for this purpose. Today's proposal therefore provides for the assignment of priorities to significant source categories for the development of these regulations, through publicly stated criteria and announced decisions.

Under today's proposal, source categories posing significant risks will be assigned priority status (high, medium, or low) for further regulatory action (beyond generic standards) on the basis of: (1) the magnitude of projected total excess cancer incidence associated with current and future source emissions; (2) magnitude of cancer risks for the most exposed individuals; (3) ease of expeditious standards development and implementation; and (4) feasibility of significant improvements in controls. In addition, significant sources of more than one carcinogen may be given priority over single-pollutant sources, based on the sum of risks from the emitted substances.

A high priority will be assigned, for example, to a source category constituting an important problem requiring immediate attention, or where risks are somewhat lower but an appropriate regulatory solution is both feasible and readily available. Source categories assigned medium priority will generally be those that present lower risks and will be scheduled for standard development as resources become available. Lower risk source categories for which the extent of feasible control may be substantially limited will be assigned low priority for regulation development. Assignment to the low priority category will generally mean that active development of regulations will not begin until there is some change in the factors which led to the assignment, or until higher priority actions have been completed.

(c) *Regulatory Options Analysis.* EPA will perform detailed analyses to identify alternative, technologically feasible control options and the economic, energy, and environmental impacts that would result from their application. Where substitution is determined to be a feasible option, the benefits of continued use of the substance or process will be considered. These analyses will rely primarily on the procedures and techniques employed by EPA for developing New Source Performance Standards under section 111 of the Act.

The identification of feasible control options will initially survey the existing control devices at the sources within a particular category to determine the best controls currently in use. The potential emission points of the listed pollutant at a particular kind of facility will also be identified, as will possible emissions of carcinogens other than the specific one under study. EPA will, in addition, examine the applicability of available technologies which are not currently

[9] The CPSC interim policy has been rescinded, 44 FR 23821 (April 23, 1979).

used by the industry to control the pollutant of concern (technology transfer) but which have been demonstrated in pilot tests or other industrial applications. Finally, the availability and adequacy of substitutes which would eliminate some or all emissions of the pollutant will be assessed.

Once the technologically feasible control alternatives, which may range from no further control to a complete ban on emissions, have been identified, the environmental, economic and energy impacts of these options will be determined. Considerations in these impact assessments will include for each option: the number of plant closures predicted and the direct impact on employment and end product prices; the impact on growth and expansion of the industry; the resulting changes in profitability; capital availability for control equipment; the impacts from the availability of substitute products and foreign imports; the potential increases in national energy consumption; and the impacts on other environmental medial including increased water pollution and solid waste disposal. On the basis of these assessments, one of the control options identified will be designated as the "best available technology" for the control of emissions from the sources in the category. This level of control will be that technology, which in the judgment of the Administrator, is the most advanced level of control adequately demonstrated, considering economic, energy, and environmental impacts.

The control level designated "best available technology" may be different for new and existing facilities in a category. For practical purposes, this level of control for new sources will, as a minimum, be equivalent to that which would be selected as the basis for a New Source Performance Standard (NSPS) under section III. The requirement of "best available technology" for new sources would consider "economic feasibility" and would not preclude new construction.

The selection of BAT for existing sources may require consideration of the technological problems associated with retrofit and related differences in the economic, energy, and environmental impacts. In practice, BAT for existing sources would consider economic feasibility and would not exceed the most advanced level of technology that at least most members of an industry could afford without plant closures.

(d) *Minimum Requirements for Existing Sources.* Final section 112 standards will require existing sources in any regulated source category, as a minimum, to limit their emissions to the levels corresponding to the use of "best available technology." This requirement is based on the Administrator's' judgment that any risks that could be avoided through the use of these feasible control measures are unreasonable. Whether BAT controls are sufficient to protect public health will be determined by a subsequent evaluation of the remaining risks.

(e) *Determination of Unreasonable Residual Risk for Existing Sources.* Following the identification of BAT for existing sources, the quantitative risk assessment described earlier will be used to determine the risks remianing after the application of BAT to the source category. If the residual risks are not judged by the Administrator to be unreasonable, further controls would not be required. If, however, there is a finding of unreasonable residual risk, a more stringent alternative would be required. Among the possible alternatives would be the immediate application of more restrictive emission standards, including those based on more extensive use of substitutes, and scheduled or phased reductions permissible emissions. The alternative selected would be that necessary, in the Administrator's judgment, to eliminate the unreasonable residual risks.

Given the differences in the degree of certainty in risk estimates, in the numbers of people exposed, in benefits, in the distribution of risks and benefits, in the costs of controls, in the availability of substitutes, and in other relevant factors, it is not possible to state any precise formula for determining unreasonable residual risk. The determination will necessarily be a matter of judgment for each category involved. Nevertheless, the process followed and the various factors involved can be outlined.

The determination of unreasonable residual risk will be based primarily on public health, and will require protection with an ample margin of safety. To the extent possible, quantitative or qualitative estimates of various factors will be made for purposes of comparison. Among these are: (1) the range of total expected cancer incidence and other health effects in the existing and future exposed populations through the anticipated operating life of existing sources; (2) the range of health risks to the most exposed individuals; (3) readily identifiable benefits of the substance or activity; (4) the economic impacts of requiring additional control measures; (5) the distribution of the benefits of the acitivity versus the risks it causes; and (6) other posseible health and environmental effects resulting from the increased use of substitutes.

(f) *The Degree of Control Required for New Sources.* The need to focus independently on new sources of carcinogenic emissions stems principally from the nature of the threat posed by airborne carcinogens. Because of the lag time betweeen exposure to a carcinogen and onset of the disease, any assessment of the magnitude of the problem posed by current exposure levels is subject to considerable uncertainty, since the consequences have not yet become manifest. Decisions on the appropriate level of control must take into account the possibility that the dimensions of the current problem have been underestimated.

It also appears likely that the activities causing current carcinogenic emissions will continue to expand, and that new ones will appear. Since new emissions would threaten an increased cancer incidence, it is incumbent upon the Agency to meet that threat in advance, especially if that can be done free of some of the constraints associated with the reduction of risks from existing sources.

The policy of developing separate requirements for new sources is based on two additional considerations. First, many of the factors affecting risks can be controlled to a significant extent before new construction takes place. Foremost among these factors is siting: new sources in heavily populated areas create much greater cancer risks than those locating in less populated areas. In addition, new sources can sometimes apply control technology more cheaply and effectively than existing sources, since new sources: (1) are often larger and can thus benefit from the economies of scale; (2) can engineer the integration of emission controls from the ground up; and (3) do not have existing control equipment which must be dismantled or scrapped.

Second, given these differences, a determination of the appropriate control level for new sources on the basis of unreasonable residual risk may also weigh the relevant factors differently. While the focus for existing sources is primarily the balancing of health risks against the costs of retrofit controls beyond BAT, for new sources the balance can focus more heavily on siting, the benefits of the activity, and the possibility of fundamental changes in the process which would lower emissions.

For these reasons, the Administrator proposes to include in this policy a mechanism dealing specifically with new sources. Under this mechanism,

described in more detail below, the standards applicable to new and modified sources would be determined on a case-by-case basis, and would consist of either (a) a presumptive emission standard, (b) the best available technology standard, or (c) an alternative standard. Regulations concerning procedures for the approval of construction or modification under section 112 standards (40 CFR 61.07) would be amended to reflect the requirements of the proposed policy, if it is adopted.

The Administrator recognizes that the mechanism proposed here is somewhat complex. After extensive consideration, however, this procedure appears to be the approach most likely to satisfy the policy and practical needs described above, within the constraints imposed by section 112. The Administrator actively solicits comment on the procedure, and particularly on possible alternative means to achieve the same objectives.

(1) Presumptive Emission Standards

EPA will prescribe a presumptive national emission standard for each regulated source category. This standard will prescribe a maximum emission rate and will be based solely on potential health effects. The presumptive standard will be designed to preclude the existence of significant risks under projected worst case assumptions of plant size and emissions, surrounding population density and distribution, and meteorology. Any proposed new source which would meet this limit would be certified for construction under section 112(c) (1)(A) without further demonstration or analysis.

(2) Waiver to Best Available Technology

Any new source meeting Risk Avoidance Criteria (described below) specified for each regulated source category will be granted an automatic waiver of the applicable presumptive emission standard, and will instead be required to meet the best available technology standard. Risk Avoidance Criteria will be designed to recognize actual conditions more favorable than the worst case assumptions used as the basis for the presumptive emission standard. Waivers will be granted, upon application of the source during the certification process, where, as a result of those different conditions, emissions greater than the level of the presumptive emission standard would not result in risks greater than those associated with the presumptive emission standard. The criteria to be met, in general form, are:

(a)(1) Population density and distribution around the proposed site at the sources's proposed emission rate are within limits specified by EPA. These limits will be set to allow carefully-sited sources, whose emissions using best available technology under specified siting conditions would not result in significant risks, to receive automatic waivers; and

(2) The proposed source is not within a specified distance of a source of carcinogens regulated under section 112; or

(b) An offset against new emissions can be obtained either internally (existing sources seeking to expand) or from existing sources of carcinogens regulated under section 112 within a specified distance. This criterion is intended to allow automatic waivers to best available technology where exposure to people already at risk from recognized carcinogenic emissions would not increase as a result.

(3) Establishment of Alternative Standard

Any proposed source unable to qualify for an automatic waiver to best available technology would be eligible to apply to EPA for the establishment of an alternative standard applicable to that source. The alternative standard would be based on the avoidance of unreasonable residual risk after the use of best available technology, and may range from the presumptive emission standard to best available technology. In establishing an alternative standard, the Administrator would generally consider the same factors as in an unreasonable residual risk determination for existing sources. The relevant factors include:

(a) the range of total expected cancer incidence and other serious health effects associated with emissions of the source throughout its anticipated operating life;

(b) the range of health risks to the most exposed individuals from the source's emissions;

(c) existing risks to the affected population from emissions of the listed pollutant and other carcinogenic air pollutants;

(d) readily identifiable benefits of the substances or the activity producing the risk;

(e) the economic and technological feasibility of further control measures;

(f) the distribution of the benefits of the activity versus the distribution of risks;

(g) other possible health effects resulting from the use of substitutes for the substance or activity; and

(h) the extent to which possible emissions offsets may be obtained.

(3a) Summary of the Legal Basis for Proposed EPA Standard-Setting Approach

As noted earlier, EPA has experienced considerable difficulty in interpreting and applying the requirement of "an ample margin of safety to protect the public health" in setting standards for carcinogenic air pollutants under section 112 of the Clean Air Act. The factual aspects of the problem are first, as explained above, that airborne carcinogens appear to have no identifiable thresholds (minimum exposure levels) for adverse health effects; second, that in many cases the individual risks they present at ambient concentrations may be extremely small; and third, that total elimination of those risks could require the closure of some of the nation's basic industries. The corresponding problem of legal interpretation is that Congress does not appear to have addressed this situation when enacting section 112.

For the reasons discussed in more detail in the supplemental statement of basis and purpose following this notice, the Administrator has concluded that although it is possible to read section 112 as requiring regulation designed to protect health absolutely, Congress has not expressed any clear intention to require the total elimination of risks posed by carcinogenic air pollutants. The Administrator therefore believes that, in light of the legislative history of section 112 and of the Act as a whole, the most reasonable interpretation of that section requires him to focus principally on health protection in regulating airborne carcinogens but does not require the total elimination of risks from such substances. Consequently, it is the Administrator's judgment that standards set under the policy proposed today will protect the public health with an ample margin of safety. These conclusions are reinforced by the likelihood that Congress would have provided much clearer guidance had it intended the drastic results that would flow from a requirement to eliminate totally all risks from airborne carcinogens.

(4) Public Notification and Involvement

(a) *Screening, Identification, and Assessment.* The results of the preliminary screening process, determinations of carcinogenicity, preliminary exposure analyses, and decisions on listing, proposal of generic regulations, and further analysis and testing will be published in the Federal Register. This notification will serve to advise the public, state and local agencies, and industry of the potential

hazards associated with the substances examined, will indicate which substances are receiving further attention, and will request the involvement of interested parties.

(b) *Listing, Quantitative Risk Assessments, and Determination of Regulatory Priorities.* The development of regulations is a time-consuming process. While the use of generic standards and the initial focus on regulating the most significant sources first will accelerate the process of reducing risks to public health, it is likely that regulation of medium and lower priority sources will not be completed for a number of years. To insure that the public, industry, and the states are aware of the status of federal regulatory efforts, the results of risk assessments and priority determinations will be published in the Federal Register. These notices will include decisions and recommended actions on all substances under review.

(c) *Proposal and Promulgation of Standards.* Upon the proposal of generic or final regulations for source categories of listed airborne carcinogens, EPA will hold public hearings and solicit written comments on the proposed rulemaking. Records of such hearings and comments received will be made available for public inspection through the maintenance of public dockets.

(5) Preparation of Regulatory Analyses

This proposal is classified as a major regulation under EPA's final report implementing Executive Order 12044 "Improving Government Regulations" (44 FR 30988) in that it addresses a "major health or ecological problem." The Executive Order requires that a regulatory analysis of potential economic impacts be prepared for major regulations meeting certain criteria. The criteria are, in brief: 1) additional costs of compliance totalling $100 million; 2) additional costs of production exceeding 5 percent of the selling price of the product; or 3) the Administrator requests such an analysis.

The procedures outlined in the proposed rule are intended to guide the Agency in the identification and control of airborne carcinogens under the principal authority of section 112 of the Clean Air Act. The policy does not impose regulatory requirements on any emission source and, therefore, does not meet either of the economic criteria for preparing a regulatory analysis. The purpose of the policy is to establish a framework for EPA decisions including the conduct of economic and risk analyses of subsequent regulatory actions. To attempt to quantify the impact of future regulations requiring unidentified controls on unknown source categories of, as yet, unnamed pollutants would not, in the judgment of the Administrator, be a meaningful exercise.

While an economic analysis is not considered appropriate for this proposed procedural rule, EPA has considered possible regulatory alternatives. A discussion of relevant issues is presented in the supplemental statement of basis and purpose which follows the text of the proposed rule.

(6) Periodic Review

At intervals of no more than five years, regulations promulgated for each source category of airborne carcinogens will be reviewed for possible modification, based on recent technological developments and any new health effects information available. This will provide an opportunity to consider the tightening of standards for existing sources to reflect new technology, and the application of innovative technologies for new sources. At the conclusion of each review, standards will be revised to reflect more stringent control requirements, or the existing standards may be reaffirmed, as appropriate.

(Sections 111, 112, and 301(a) of the Clean Air Act, as amended, 42 U.S.C. sections 7411, 7412, and 7601(a).)

Dated: August 22, 1979.

Douglas H. Costle,

Administrator.

The Administrator proposes to add the following rule as Appendix C to Part 61 of Title 40 of the Code of Federal Regulations:

Appendix C—Policy and Procedures for Identifying, Assessing, and Regulating Airborne Substances Posing a Risk of Cancer

I. Introduction

A. Scope of Rule

This rule specifies the policies used by EPA in the regulation of stationary sources of potentially carcinogenic air pollutants under relevant Clean Air Act authorities, principally section 112. The rule does not affect regulation of non-carcinogenic hazardous substances under section 112[10] or supplemental regulation of airborne carcinogens under other Agency authorities where applicable.

B. Statement of General Policy

(1) The EPA policy for regulation of sources emitting airborne carcinogens under section 112 of the Clean Air Act is to protect the public health with an ample margin of safety. This protection will be achieved by requiring the elimination of unreasonable residual risks from existing sources as quickly as possible, and by preventing the development of such risks from new sources.

(2) The presence of "unreasonable residual risks" to an affected population will be determined independently for each category of sources regulated. Primary emphasis in this determination will be on the level of risk remaining after the installation of the "best available technology" for the control of emissions from sources in the category. In evaluating this risk, consideration will be given to the benefits conferred by the substance or activity, the distribution of those benefits versus the distribution of the risks presented by the substance or activity, the availability of substitutes, the cost of further control of the substance or source category, and the proposed siting of new sources.

II. Preliminary Assessment of Health Risks

A. Identification of Candidate Substances

Potential airborne carcinogens (candidate substances) will be identified through EPA programs, including searches of the scientific literature, monitoring studies, and biological assays of substances found in the ambient air and source emissions, as well as by examining information obtained from federal, state, or other public testing or regulatory authorites, private research groups, and other scientific sources.

B. Screening

Candidate substances will be screened to determine the potential extent of exposure of the public through air emissions.

(1) Screening of candidate substances will consist of an analysis of readily available information on their production, uses, properties, air concentrations, and of other indices useful in assessing the potential for public exposure. EPA will also ascertain whether any other regulatory efforts are in progress with respect to these substances.

(2) Substances which the identification and screening process indicates (a) may be carcinogenic and (b) the public probably is exposed to via the ambient air will be evaluated to determine whether they pose a significant carcinogenic risk to the public. Substances with the greatest apparent potential for public exposure will be given highest priority for this further examination.

C. Preliminary Evaluation of Risk

The preliminary evaluation of the risks posed by a candidate substance will consist primarily of an evaluation of the probability that it is a human carcinogen and a preliminary evaluation of the extent of ambient exposure.

(1) *Evaluation of the Probability of Human Carcinogenicity.* Evaluation of the probability that a substance is a human carcinogen will be performed using criteria adopted by EPA for such determinations. These currently applicable criteria are summarized in the Interim Guidelines for Carcinogen Risk Assessment (41 FR 21404; May 25, 1976). Using these criteria, the weight and quality of evidence of human carcinogenicity for

[10] A substance may also be regulated under section 112 due to its non-carcinogenic health effects, or due to a combination of carcinogenic and other serious effects. Non-carcinogenic effects of substances being reviewed as possible airborne carcinogens will also be evaluated and considered where information on these effects is available.

candidate substances will be assessed. Based on such assessments, including comparison with other substances which have been evaluated for regulatory action, a judgment of the probability that a substance is a human carcinogen for regulatory purposes will be made roughly as follows:

(a) High Probability of Human Carcinogenicity—Substances for which "best" or "substantial" evidence exists from epidemiological and/or at least one mammalian study.

(b) Moderate Probability of Human Carcinogenicity—Substances for which "suggestive" evidence exists from epidemiological, animal, or "short-term" studies.

(c) Low Probability of Human Carcinogenicity—Substances for which only "ancillary" evidence exists, such as from structural correlations, or for which epidemiological or animal results are judged to indicate low probability.

(2) *Preliminary Evaluation of Ambient Exposure.* EPA will also conduct preliminary evaluations to determine whether source emissions of high-probability carcinogens exist which cause or contribute to air pollution posing significant carcinogenic risks to the public. Among the factors that this evaluation may take into account are the number and types of sourses emitting the substances in areas where people may be exposed, the volume of their emissions, any ambient concentrations which may have been reported, and the number of people living near emitting sources or in the vicinity of ambient measurement sites. Where available, estimates of carcinogenic strength may be used to compute preliminary quantitative estimates of lifetime individual risks to the potentially most exposed individuals.

III. Initial Responses to Preliminary Assessment of Health Risks

A. Listing

Substances judged by the Administrator to present significant carcinogenic risks to the public will be listed under section 112 as hazardous air pollutants. A substance will be judged to present a significant carcinogenic risk if (1) it is judged by the Administrator to have a high probability of being a human carcinogen, and (2) there is evidence of significant public exposure via the ambient air from emissions from one or more categories of stationary sources. Where the available evidence is otherwise insufficient to indicate the existence of a significant risk, a high-probability carcinogen also will be listed under section 112 if a preliminary quantitative risk estimate suggests that a significant risk to the potentially most exposed groups exists. Where emissions or exposure data indicate the existence of a significant risk, quantitative risk estimates will not be considered evidence to the contrary.

B. Generic Standards

Upon the listing of a substance, previously-developed generic standards will be proposed for source categories of that substance to which they could apply. Generic standards, developed based on the similarities among industrial processes, will be "tailored" as necessary to fit the source categories for which they are proposed.

C. Moderate-Probability and Low-Probability Carcinogens

EPA will recommend or require further biological testing of substances initially judged to have a moderate or low-probability of being human carcinogens. Priorities for testing will be based on the extent of public exposure. Moderate-probability substances for which public exposures appear to be high will be considered for regulation under section 111 of the Clean Air Act.

D. Quantitative Risk Assessments

Quantitative risk assessments on all high-probability carcinogens will be performed, if possible. These assessments will be undertaken based on priorities designed to produce action most quickly on the most serious problems pending at any given time. The results of these assessments will be used in the assignment of priorities for further regulation and in the evaluation of residual risks.

(1) The risk assessments will examine:

(a) detailed information on emission sources of the pollutants, the sources' control status and total emissions, measured and predicted ambient concentrations of the pollutants, and the production levels and uses of the substances;

(b) distribution of the population around sources in specific sources categories;

(c) estimated duration and magnitude of exposures of the affected population and the most exposed individuals;

(d) estimated carcinogenic strength (potency) of the substances;

(e) estimated range of expected cancer incidence for the total population and individual risks for the most exposed individuals at various possible emission levels;

(f) other serious health effects of the substances; and

(g) projected population growth around existing sources.

(2) The criteria to be considered in assigning priorities for quantitative risk assessments include, in usual order of importance:

(a) probable extent of exposure of the public through air emissions;

(b) estimated carcinogenic strength;

(c) the effect of any generic standards proposed; and

(d) the feasibility of expeditious control.

(3) The results of detailed risk assessments and determinations resulting from the assessments will be published in the Federal Register and public comments will be solicited.

IV. Establishment and Review of Standards and Requirements

A. Source Categories Regulated

Emission standards in addition to generic standards will be proposed for any source category whose emissions present a significant risk to public health. Such standards and other requirements will be determined independently for each regulated source category. A source category emitting a listed pollutant will be found to pose a significant risk if there is evidence, from the detailed exposure analysis, that its emissions result in significant public exposure to the pollutant via the ambient air. Significant risk also will be found in the absence of such evidence, if a detailed risk assessment suggests that such a risk to the most exposed individuals or to the population exists. If emissions or exposure data indicate the existence of a significant risk, the quantitative risk assessment will not be considered as evidence to the contrary.

B. Priorities for Further Regulation

Further standards and requirements for regulated source categories will be developed according to the priority assigned to those source categories. Source categories will be assigned high, medium, or low priority based on the following criteria:

(1) magnitude of the total expected and upper bound cancer incidence associated with exposure to all carcinogens emitted by the source category;

(2) degree of risk to the most exposed individuals;

(3) ease of expeditious development and implementation of standards; and

(4) feasibility of significant improvements in controls.

C. Regulatory Options Analysis

EPA will conduct a regulatory options analysis to support decisions on further required control measures.

(1) The analysis will identify technologically feasible control alternatives, their economic, energy, and environmental impacts, and, in the case of substitutes, the benefits of continued use of the substance or process.

(2) The analysis will also designate levels of control considered "best available technology" for new and for existing sources in a category. The control level designated "best available technology" may be different for new and existing facilities in a category.

(a) For new sources, "best available technology" is that technology which, in the judgment of the Administrator, is the most advanced level of controls adequately demonstrated, considering economic, energy, and environmental impacts.

(b) For existing sources, "best available technology" is that technology which, in the judgment of the Administrator, is the most advanced level of controls adequately demonstrated, considering economic, energy, environmental impacts, and the technological problems associated with retrofit.

D. Requirements for Existing Sources

(1) Existing sources in a regulated source category will be required, as a minimum, to limit their emissions to the levels corresponding to the use of "best available technology".

(2) Existing sources in a regulated source category also will be required to limit their emissions in whatever additional amount is necessary, in the Administrator's judgment, to eliminate unreasonable residual risks to public health associated with those emissions.

(3) The principal emphasis in determining the level of additional control required to

eliminate unreasonable residual risk from an existing source category will be on public health. Factors which may be considered in this judgment include:

(a) the range of total expected cancer incidence and other serious health effects in the existing and future populations exposed, for the anticipated operating life of existing sources in the category;

(b) the range of health risks to the most exposed individuals;

(c) readily identifiable benefits of the substance or activity producing the risk;

(d) the economic effects (especially plant closures) of requiring additional control measures;

(e) the distribution of the benefits of the activity versus the distribution of its risks; and

(f) other possible health effects resulting from the increased use of substitutes.

E. Requirements for New (Including Modified) Sources

(1) Except as provided below, new sources in a regulated source category will be required to meet a presumptive national emission standard designed to preclude the existence of significant risks under projected worst case assumptions of plant size and emissions, surrounding population density and distribution, and meteorology.

(2) Any proposed new source which shows, in the certification process required by section 112(c)(1)(A), that it meets the requirements of the Risk Avoidance Criteria (described below) applicable to that source category will automatically be permitted to meet the applicable best available technology standard instead of the applicable presumptive national emission standard. The specific terms of Risk Avoidance Criteria will be prescribed separately for each source category.

The criteria will generally require that either:

(a)(1) Population density and distribution around the proposed site at the source's proposed emission rate are within limits specified by EPA, and

(2) The proposed source is not within a specified distance of a source of carcinogens regulated under section 112; or

(b) An offset against new emissions can be obtained either internally (existing sources seeking to expand) or from existing sources of carcinogens regulated under section 112 within a specified distance.

(3) Any proposed new source which is unable to qualify for the automatic waiver to best available technology described in paragraph (2) may apply for the establishment of an alternative standard applicable to the proposed source as part of the certification process required under section 112(c)(1)(A). The Administrator will establish an alternative standard for that source at the best available technology standard or at whatever more stringent level of control is necessary, in his/her judgment, to prevent the existence of an unreasonable residual risk associated with emissions from the proposed source. Factors which may be considered in this judgment include:

(a) the range of total expected cancer incidence and other serious health effects associated with emissions of the source throughout its anticipated operating life;

(b) the range of health risks to the most exposed individuals from the source's emissions;

(c) existing risks to the affected population from emissions of the listed pollutant and other carcinogenic air pollutants;

(d) readily identifiable benefits of the substance or the activity producing the risk;

(e) the economic and technological feasibility of control measures more stringent than BAT;

(f) the distribution of the benefits of the activity versus the distribution of its risks;

(g) other possible health effects resulting from the use of substitutes for the substance or activity; and

(h) the extent to which possible emission offsets have been obtained.

F. Review of Standards and Requirements

Regulations promulgated for each source category of airborne carcinogens will be reviewed and, if appropriate, revised at intervals of no more than five years.

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[Note.—This Supplemental Statement will not appear in the Code of Federal Regulations.]

Policy and Procedures for Identifying, Assessing, and Regulating Airborne Substances Posing a Risk of Cancer

Supplemental Statement of Basis and Purpose

This document is intended as an elaboration of three aspects of the basis and purpose of EPA's proposed rule for the regulation of airborne carcinogens. It should be read in conjunction with the preamble to the Notice of Proposed Rulemaking for this action, which it supplements. The three aspects of the background of the proposal which are discussed in this supplement are: (1) a comparison of the EPA proposal with recent proposals of other Federal agencies for regulating carcinogens; (2) various regulatory approaches considered by the Administrator in formulating the proposed rule; and (3) a fuller explanation of the underlying view of the meaning and intent of section 112 of the Clean Air Act which led the Administrator to choose the standard-setting approach actually proposed.

I. Comparison With Other Proposals

The policies and regulatory approaches reflected in EPA's proposed rule are similar in many important respects to those contained in recent proposals by the Occupational Safety and Health Administration (OSHA) (*1*) and the Consumer Product Safety Commission (CPSC) (*2*). There are also a number of similarities to proposals made to EPA and other agencies by the Environmental Defense Fund (EDF) (*3*) and to some extent by the American Industrial Health Council (AIHC) (*4*). The most important similarities and differences among the various proposals are described below.

The critical areas for comparison of the various proposals are: (1) the scientific criteria underlying determinations of carcinogenicity for regulatory purposes; (2) the use of those criteria in automatic classification systems; (3) the regulatory response to determinations of carcinogenicity; and (4) the role of quantitative risk assessments.

A. Carcinogenicity Criteria

The scientific criteria for determination of carcinogenicity under the OSHA, CPSC, and EDF proposals are similar to the EPA Interim Guideline for Carcinogen Risk Assessment (*5*). All accept epidemiology as best evidence but presume human cancer risk as a result of animal data alone. All accept the principle that there is no safe level of exposure to carcinogenic substances. Differences between the EPA and OSHA criteria are discussed in some detail in the EPA testimony at the OSHA hearing. The major difference is that EPA may consider the results of a single well-conducted animal study as sufficient to classify a substance a high probability carcinogen, while the OSHA proposal requires replication of such a study or a second "postive" study in a different species. EPA feels that such a requirement is scientifically unnecessary where the original study is of sufficient quality and could result in unnecessarily long delays while retesting takes place.

Although the general scientific principles are similar, the OSHA and CPSC statements are considerably more specific on a number of points than are the EPA guidelines. EPA believes that greater specificity and agreement among the agencies are desirable, where possible, and has joined with the Occupational Safety and Health Administration (OSHA), Consumer Product Safety Commission (CPSC), Food and Drug Administration (FDA), and Food Safety and Quality Service (FSQS) in the Interagency Regulatory Liaison Group (IRLG) for the purpose of developing a uniform scientific basis for determining the probability that a substance is carcinogenic. The IRLG has recently published a document dealing with these issues (*6*). Once the document becomes final, the rule proposed today will be amended if necessary and those principles will be used by EPA in regulating airborne carcinogens under section 112.

There are a number of differences between the methods recommended by AIHC for carcinogenicity determinations and EPA's Interim Guideline. In particular, AIHC suggests that greater weight be given to negative epidemiological studies; that single-species animal studies are insufficient to make a presumption of human carcinogenicity; and that short-term test results are unsuitable for use in regulatory decisions.

EPA feels that while "negative" epidemiological evidence can sometimes provide upper bounds on possible risks, epidemiology is normally not a sensitive enough tool to provide proof that a substance which is carcinogenic in animals is not carcinogenic in humans. EPA considers well-conducted single species tests and single tests results substantial evidence of carcinogenicity. Such tests are widely used in industry and government laboratories. In light of the available evidence, delaying the implementation of controls for three or more years while confirmatory tests are conducted would not be a prudent policy. The Agency feels that existing experience with short-term tests is sufficient to suggest including results along with other evidence in deciding the likelihood of carcinogenicity. In summary, EPA feels that, given the available scientific evidence, protection of public health requires the use of the criteria outlined in the Interim Guideline.

The AIHC also recommends establishment of a nine-member panel to evaluate and classify carcinogens for all Federal agencies, suggesting that identification and classification of carcinogens is too important and too complicated to be left to government regulators alone. EPA believes, however, that there would be little advantage to this approach. Agreement among the IRLG agencies should make it unlikely that these Federal agencies would reach inconsistent conclusions about a substance's carcinogenicity. Having a single group—whether it be one agency or an outside group of scientists—perform these evaluations would only add another layer of review, which could create serious problems. Among other things, establishing priorities that would accomodate the needs of all affected agencies with their many different regulatory responsibilities and deadlines would be complex and resource-intensive. In addition, if an outside group of scientists were used to evaluate cancer risks, the scientists might be reluctant to take positions on substances for which data are not definitive. This would conflict with the agencies' obligation to act upon the best available information rather than to await definitive evidence. Finally, it should also be noted that current EPA procedures include an evaluation of carcinogenicity determinations and risk assessments by the EPA Science Advisory Board, a review panel consisting of scientists from outside of the Federal government.

The AIHC makes no clear recommendation on techniques to be used in evaluating excess cancer incidence other than to recommend that carcinogen strength and cancer risks be evaluated as part of the regulatory process. As EPA's proposal indicates, the Agency agrees that carcinogenic strength and risk should play a role in that process.

B. Classification Systems

In testimony at the OSHA hearings, EPA articulated its reservations about the use of rigid, fixed criteria and automatic classification schemes. EPA is concerned that, since each determination is to some extent unique, rigid classification schemes may not provide enough room for the use of informed scientific judgment in making carcinogenicity determinations. Examples of the Agency's concerns are discussed in the EPA testimony (*7*). EPA, therefore, prefers to continue to use a "weight of evidence" approach which allows the use of informed

scientific and policy judgments in evaluating test results.

C. Response to Determinations of Carcinogenicity

Under the policy proposed by OSHA (upon which the EDF petition is modeled), substances classified as "confirmed carcinogens" would be automatically regulated through an immediate emergency temporary standard including exposure limits, monitoring, and work practices. Within six months, a permanent standard would be proposed to: (1) effectively ban the substance if a suitable substitute were available and (2) require exposures to be reduced to lowest feasible level through technological means.

The approach published by the CPSC establishes procedures for identification and classification of carcinogens based on scientific criteria and categories similar to those proposed by OSHA. A major difference between the CPSC and OSHA approaches is that if a substance is identified as a confirmed carcinogen ("Category A"), CPSC would not automatically propose a particular regulatory action. Instead action would be taken on a case-by-case basis, after a study of relevant factors.

EPA believes that the appropriate regulatory response following the listing of an airborne carcinogen under section 112 must take into consideration more than a determination of carcinogenicity. Given the large number of potential airborne carcinogens, some means of establishing priorities for regulating those substances posing the greatest public health risks is necessary to ensure that available Agency resources are used to the greatest effect. The set of initial regulatory responses in the proposed EPA rule is designed to accomplish that by accelerating the process of listing and initial regulation, and by enabling the Agency to address the most significant sources and substances first.

The CPSC policy also recognizes the need for such procedures. The system for setting priorities for assessment proposed by EPA is conceptually similar to that adopted by CPSC for establishing priorities for staff evaluation and Commission appraisal of consumer products containing carcinogens.

The OSHA and EDF proposals do not contain explicit procedures for the establishment of priorities after carcinogenicity determinations. Those proposals would entail a fairly rigid schedule of regulatory responses to notification or discovery of potential carcinogenicity. After carcinogenicity determinations, both the OSHA and EDF schemes would require automatic responses without explicit consideration of risks or other indices of relative priority.

One element of the OSHA proposal is the immediate imposition of an emergency temporary standard. The response is somewhat analogous to the "generic standards" element of today's proposal. Like OSHA, EPA believes that there is no reason to permit the continued exposure to risks which could be prevented by the use of clearly feasible control measures. EPA views the implementation of such measures as a high priority matter, especially since the application of pre-existing generic standards to specific sources will not divert significant Agency resources from other control efforts.

EPA also believes, however, that a system for establishing priorities for further regulatory actions is necessary in effectively implementing section 112. The Agency does not believe that a full system of automatic responses, such as that proposed by OSHA, would be feasible for use under section 112, both because of the large number of airborne carcinogens likely to be encountered and because of the differences in the statutory and practical tasks EPA must perform.

D. Role of Quantitative Risk Assessment

It is not celar what role, if any, quantitative risk estimates would play in the approach OSHA intends to employ. As noted earlier, EPA believes that, while cancer risk estimation is an imprecise endeavor involving many uncertainties, such estimation can provide a rough measure of the magnitude of carcinogenic risk posed by a substance. EPA believes that consideration of such estimates in establishing regulatory priorities and in determining the degree of additional control required beyond BAT is both useful and appropriate under section 112. This is particularly true in the Administrator's view with respect to exposures to carcinogens in the ambient environment, which, in contrast to occupational exposures, can often be very low and involve large populations. Like OSHA, however, EPA does not view these estimates as required for the decision that a particular substance being emitted into the air should be regulated as a hazardous pollutant, once a determination of probable carcinogenicity and significant exposure has been made.

II. Various Regulatory Approaches Considered

A central issue in developing a policy for the protection of public health from carcinogens is the determination of the extent to which exposures must be reduced. Given the impossibility of identifying levels of carcinogens with no associated risk, some have argued that no exposure should be tolerated and that emissions should be reduced as expeditiously as practical to zero. Others contend, on the contrary, that permissible exposures should be determined by an unstructured balancing of risks, costs, and benefits.

A number of approaches for addressing this problem have been considered or proposed by the Federal regulatory agencies, industrial groups, environmental organizations, and others. Prominent examples include the OSHA proposal 1, the CPSC policy (2), and the EDF petition (3) on airborne carcinogens. This section discusses various suggested possibilities that have been considered by EPA, as well as the approach proposed today.

The possibile approaches and schemes suggested fall into essentially four groups: zero-oriented approaches; predetermined decision rules; special approaches for new sources; and judgmental approaches. The charcteristics of these approaches are discussed below in terms of their possible usefulness in regulating carcinogens under section 112 of the Clean Air Act.

A. Zero-Oriented Approaches

As discussed above, the lack of identifiable health effects exposure thresholds for carcinogens suggests that exposure to even minute amounts of such substances poses some finite risk, and that repeated exposures increase the risk. This has led to the proposition that for public health purposes, no level of exposure to carcinogens can be considered absolutely "safe." In particular, because section 112 emission standards must protect the public health with an ample margin of safety, it has been argued that those standards must therefore eliminate risk completely.

The Administrator believes that his goal in administering section 112 must be to reduce exposures to carcinogens to the maximum extent possible. While this implies at least a theoretical goal of zero emissions of these substances, the immediate imposition of zero-emission requirements would lead to the closing of most facilities now emitting carcinogenic air pollutants. It is not now physically possible, for example, to manufacture, handle, and store volatile organic compounds without some emissions, however small.

As noted earlier, the Administrator does not believe that the immediate imposition of zero-emission standards on a general basis, with their attendant consequences, is appropriate under section 112. Nevertheless, in setting section 112 emission standards, public health considerations must be paramount. Various mechanisms designed to minimize risk as part of certain zero-oriented approaches may therefore be useful for purposes of section 112. These mechanisms include:

(1) *Immediate Emission Control Requirements Beyond the use of Best Available Technology.* Standards more restrictive than those achievable through the use of "best available technology" for existing sources, effective within between ninety days and two years of promulgation, could result in the closure of some sources.[11] Depending on the degree of additional control judged necessary, and on particular economic and technological factors, this could range from a few older, marginal facilities to industry closure. Such requirement may be appropriate where large residual risks remain after the use of best available controls.

(2) *Phased Control Requirements.* Although standards requiring controls beyond "best available" might not be immediately feasible for certain affected emission sources, such controls might be feasible if sufficient lead time were available before their required achievement. A form of phased control requirements, designed to force technology improvements, is suggested by EDF in its petition. This approach would involve establishing a predetermined schedule for periodic tightening of emission standards, leading ultimately to zero emissions. EPA

[11] The meaning of the term "best available technology" as used here, is explained in the principal text accompanying the proposed rule.

does not regard this particular form of phased control as well-suited for use under section 112, primarily because it fails to provide for consideration of the consequences of a zero-emissions requirement in differing circumstances, and because it could prove legally and practically infeasible for the Agency to implement.

The concept of technology forcing phased control has, however, been used in achieving ambient air standards and reducing automotive emissions, and may be employed on a more selective basis under the proposed rule. Such requirements might entail somewhat accelerated closure of older, poorly controlled plants, allowing time for funding and construction of better controlled facilities and the development of improved control technology. This approach could result in reduction of risks without extensive economic dislocation or loss of the benefits associated with the activity or substance involved.

(3) *Required Use of Substitutes.* The availability of safe and adequate substitutes for particular substances or uses can be an important factor in determining the degree of control required for a given source category. It has been suggested, in fact, that in order to eliminate emissions of the carcinogenic substance the use of substitutes should be required whenever they exist.

The main difficulty with this approach is that while partial or full substitutes are often available, their consequences vary greatly. In many cases, for example, requiring the use of substitutes can result in prohibitive economic penalties. Substitutes available for some applications are also often inadequate for other applications. Moreover, the potential health effects associated with substitutes will often be unknown. Since adequate substitutes are often similar to the original substances, they may therefore pose risks which could approach or exceed those of the banned substances.

In addition, because carcinogens can be emitted in varying amounts from such diverse sources as fireplaces, chemical plants, automobiles, dry cleaning establishments, steel manufacturing, and natural chemical and radioactive emission sources elimination of carcinogenic risks through substitution for all these activities is clearly impractical. Substitutes cannot therefore be realistically considered a solution for all or even most airborne carcinogen problems.

In establishing control requirements under section 112, consequently, EPA would consider measures requiring the use of substitutes. In reaching a decision, however, the Agency will also weigh the factors noted above to ensure that the net effect of such requirements is consistent with the other aspects of the proposed rule.

B. Predetermined Decision Rules

A number of approaches, rejecting the zero risk concept, suggest that the appropriate degree of control can be determined through uniform decision rules, applied irrespective of individual circumstances. While such decision rules vary widely in their relative emphasis on factors such as risk, cost, benefits, and technology, they share the central premise that regulatory consistency can be achieved by prescribing in advance the weight to be assigned to each of these factors under all circumstances.

Although regulatory consistency is desirable, decisions made according to predetermined rules are often unable to account adequately for unforeseen or varying circumstances. Because of the difficulty in anticipating all possible combinations of the relevant factors, decisions bound by such rules will frequently fail to produce desirable regulatory results.

EPA feels that while it is important to articulate the way in which relevant factors will be considered and weighed in determining control requirements for airborne carcinogens, the complexity and unpredictability of the situations that may arise dictate that some flexibility be maintained. Predetermined decision rules will therefore not form the principal basis for determining control requirements for airborne carcinogens under section 112. Nevertheless, some elements of decision rule approaches may be useful as benchmarks or guidelines. These approaches are discussed below.

(1) *Specification of a Fixed Target Carcinogenic Risk or Incidence Level.* This approach involves the selection of a target level of cancer risk or incidence for purposes of regulatory action, and is based on the use of quantitative risk assessment techniques. Under this approach, a fixed numerical risk or expected cancer incidence rate target would be used in determining the degree of control required for carcinogens.

The use of target risk levels does have some precedent as a basis for regulatory decisions. The FDA, for example, has regarded an upper bound lifetime cancer incidence rate of less than one per million people exposed to carcinogenic residues in certain foods as "virtually safe". EPA could theoretically establish a similar goal for airborne carcinogens for use under section 112. If the predicted risk or incidence were higher than the target, the degree of control required would be that needed to reach the goal.

While this approach might be consistent with the requirement that section 112 standards place primary emphasis on protection of public health, it suffers from two drawbacks. First, although current quantitative risk assessment techniques for chemical carcinogens are useful decisionmaking tools, considerable uncertainties are associated with the techniques at their current stage of development. Consequently, the Administrator believes that in using quantitative risk assessments, he should generally be free to consider the varying degrees of uncertainty that actual cancer risks may be significantly above or below those predicted by the estimation procedures, and not be bound by a fixed target.

Second, a fixed target risk level, used as the determinant of emissions standards, would also inadequately account for the varying conditions characteristic of air pollution. The suggested use of target risk levels instead of a zero-risk requirement is based on the importance of considering the various consequences of incremental risk reductions to levels approaching zero, and it would be inconsistent with this basis to use a fixed target risk level, irrespective of these varying consequences, in setting standards. These consequences differ greatly among source categories of air pollutants, and a fixed target fails to provide the flexibility necessary for an appropriate response. Where risks could be reduced beyond the target without significant costs, for example, that should be permitted. Likewise, where attainment of the goal would eliminate a highly beneficial activity, the decision-maker should be able to consider less stringent standards.

(2) *"Cost-Per-Life" Goals.* Some have suggested that "acceptable" standards for carcinogens may be developed by striking a predetermined balance of health risks, human lives, economics, and social benefits. Fundamental to this approach is the expression of all these factors in economic terms and the adoption of a cost-per-life-saved goal. Under this decision rule scheme, regulations would require control to, but not beyond, the point where the incremental costs associated with saving an additional life were equivalent to the goal. Proponents of this approach argue that it would result in a more optimal allocation of national resources.

The Administrator believes that several aspects of this approach render it unsuitable for standard-setting under section 112. One such aspect is the basic assumption that it is appropriate to assign a single monetary value to human life. The Administrator regards that task as neither practical nor ethically acceptable. It is impractical because no consensus criteria exist which can be used to establish that cost value. Indeed, the internalized and external expenditures for protection of human lives in American society ranges across a vast spectrum, and the very existence of this spectrum is persuasive evidence that the society places heavy emphasis on the surrounding circumstances in "assigning" health protection values. The approach is also unacceptable in that it fails to consider the balance of equities between those benefiting from the activity creating the risk and those who may die as a consequence of the activity. Finally, the fixed-cost approach also necessarily ascribes more certainty to the risk assessment and cost estimates underlying its use than is justifiable, in view of the uncertainties present in both sets of estimates. Therefore, although cost-per-life estimates may be used for perspective in considering control options, they will not be used as decision rules in setting standards under section 112.

(3) *"Best Technology".* Requirements for "best" control technology for emission sources have been advocated as an interim or ultimate approach which can be used without difficult considerations of economics in determining the degree of control required. Although such a technology-based approach at first appears relatively simple to implement, it is soon apparent that "best available technology" cannot be defined by technical considerations alone. For example, if an "add-on" control device achieves 90% control, then the installation of an additional unit of similar capabilities could reduce

remaining emissions by an additional 90%. Still further units could always be applied to marginally reduce emissions. Clearly, at some point in this process the costs associated with marginal increases in control would be grossly disproportionate to the incremental reductions in emissions. Thus, "best available technology" must be defined with at least some reference to economic considerations, as in the case of new source performance standards under section 111 of the Clean Air Act.

"Best available technology" as defined in section 111 of the Clean Air Act may not be an adequate level of control for purposes of section 112, however, since "best available technology" does not consider the health risks remaining after its use. While "best available technology" may prove a useful starting point, therefore, it is not itself sufficient for section 112 purposes without consideration of the residual health effects.

C. Special Approaches for New Sources.

A number of approaches and mechanisms have been suggested to contain or minimize increases in risks which may be associated with operation of new sources of carcinogenic air pollutants. It has been argued that special requirements for new sources are both necessary and justified because (1) given existing uncertainties about the health effects associated with exposures to various levels of carcinogens, those exposures should be limited as much as possible, and (2) new sources can reasonably consider control and risk avoidance options not readily available for existing sources. Several mechanisms for treatment of new sources are discussed below.

(1) *Stricter Standards for New Sources.* This approach would specify control requirements for new sources that are more stringent than those for existing sources. In effect, this is simply a modification of the best technology approach discussed above. The approach does have the advantage of limiting emissions from new facilities to a greater degree than from existing facilities under a best technology standard, and in that sense can be said to contain the risk somewhat.

The approach could also involve consideration of residual risks associated with projected typical new source siting conditions. However, because it cannot consider the residual health risks associated with all of the varying sets of population distributions in which a new source might actually be located, the approach may not provide sufficient protection under actual conditions. Thus, like the best technology approach for existing sources, this approach can serve as a useful starting point, but is not sufficient alone.

(2) *Regional Emissions Offsets.* An "offset" policy would require a reduction in emissions of a given carcinogenic air pollutant from existing sources in an area as a precondition for construction of new sources within a specified distance of the existing sources. To the extent that new sources desire to locate near existing facilities, development of improved emissions control technology would be encouraged by this approach and increases in risk to health beyond existing levels would be prevented.

The disadvantages of this approach as a general policy are that it would have no effect at all on the establishment of sources at new locations, and could prevent the expansion of sources which have already installed advanced technology or do not present significant new risks. In short, it employs the somewhat arbitrary assumption that any increased risk in an area with existing sources is not tolerable, but that increased risks in areas with no existing sources are permissible.

(3) *National Emissions Freeze.* Under this option, additional emissions from new or modified sources would be prohibited except to the extent that offsets are obtained from existing sources on a nationwide basis. This approach would account for some of the disadvantages of the regional emissions offset approach. It also provides incentives for technology-forcing and containment of risk.

The main drawbacks of the approach are that it presumes that any additional emissions create an intolerable risk, and that it would fall the most heavily on the newest industries (those with the fewest existing sources) and on those which have already forced technology the most. It also fails to provide incentives for careful siting of new sources.

(4) *Case-by-Case Review of New Sources.* Under this approach, additional emissions in populated or high risk areas would be permitted only after consideration of residual risks and other relevant factors associated with each new source proposed. In this review, special emphasis would be placed on appropriate siting and the use of improved control measures.

By evaluating risks, benefits, controls, and siting on a case-by-case basis, this approach could significantly limit risk without arbitrariness and over-regulation problems of either regional or nationwide offset requirements. Yet by requiring individual reviews, the pressure is maintained for both careful siting of new sources and improving technology where that appears necessary.

D. Judgmental Approaches

In contrast to the zero-oriented and fixed-decision rule approaches outlined above, "judgmental" approaches posit that the degree of control which is appropriate for airborne carcinogens cannot be predetermined in the abstract for all cases and, to some extent, depends on the particular circumstances. Circumstantial factors which might be considered, in addition to the risk to public health, include the costs of further control, the benefits of the activity, the distribution of risk versus benefits, and the availability of substitutes.

The use of a judgmental approach appears desirable to the Administrator because it permits him to take advantage of the strong points of various available approaches without suffering their drawbacks. The specific approach chosen, however, must be compatible with the mandate of section 112 to put principal emphasis on public health protection, and each of the factors involved must be assigned a weight consistent with this principle.

Although protection of public health must be paramount, the relative importance of other factors can vary. Society may be willing to pay more for control or accept higher health risks associated with activities viewed as important or essential. The distributional aspects of control situations can differ even when the magnitude of risk, costs, and benefits are similar. Moreover, differing degrees of certainty in the cancer incidence, economic, and benefits estimates can call for different regulatory responses. Given this variety of circumstances and the frequent uncertainty of analyses, the Administrator believes that it is important to consider different situations on their own merits.

Judgmental approaches obviously place great responsibility on decisionmakers to weigh the relevant factors carefully and to reach judgments in the best interest of the public. The Administrator believes that such responsibility, while heavy, is unavoidable if protection of public health is to be maximized within the constraints of a world of finite resources. The policy contained in the proposed rule is based on these views.

III. Legal Basis for the Proposed EPA Approach

A. Congressonal Intent and the Characteristics of Airborne Carcinogen

The main question the Administrator has found it necessary to answer in arriving at the interpretation of section 112 reflected in today's proposal is whether Congress, in enacting that section, had any specific intent about how an ample margin of safety would be derived in setting standards for air pollutants with the characteristics of carcinogens. If Congress had a specific intent, that would of course be conclusive. If, on the other hand, the situation presented by regulation of airborne carcinogens under section 112 falls in the interstices of congressional intent, the Administrator is required by established legal principles to deduce and impute an intent in a reasonable way that is consistent with the overall purposes and scheme of the statues.[12]

(1) The focus of congressional attention: "threshold" pollutants. In answering this question, the Adminstrator has found it helpful to recall the pollution problem that Congress perceived and addressed in 1970, when section 112 was enacted as part of a major revision of the entire Act. The legislative history of the Clean Air Amendments of 1970 reveals that the attention of Congress was at that time fixed primarily on the two problems perceived to be at the heart of the air pollution crisis: stationary source emissions of various widely prevalent pollutants such as sulfur dioxide, particulate matter, and photochemical oxidants; and automotive emissions of some of the same pollutants. The statutory scheme constructed for dealing with these pollutants reflected congressional recognition of the view that the pollutants have exposure thresholds for adverse health effects; that is, levels below which exposure to the pollutants

[12] See, e.g., *Mourning v. Family Publications Serv., Inc.*, 411 U.S. 356, 371–373 (1973); *Morton v. Ruiz*, 415 U.S. 199, 231 (1974); *United States v. Southwestern Cable Co.*, 392 U.S. 157, 171–173 (1968); *International Harvester Co. v. Ruckelshaus*, 478 F.2d 615, 643 (D.C. Cir., 1973).

would not be expected to result in adverse health effects[13]

Because it is seldom scientifically feasible to identify precisely the levels at which thresholds occur, the location of a threshold must be estimated somewhere below the exposure level (the "demonstrated effects level") at which adverse health effects have been found to occur in empirical research. Congress therefore required in section 109 of the Act that "margins of safety" be established to protect against unknown dangers below the demonstrated effects levels.[14] The Administrator believes that Congress intended health effects to be the only consideration in setting standards under section 109 under these circumstances, and this view has governed the establishment of national ambient air quality standards (NAAQS) under section 109 to date.[15]

Congress also incorporated the "margin of safety" concept, used in section 109 in dealing with the widespread apparent threshold pollutants that were at the forefront of its awareness into the requirements of section 112. The Administrator believes that this incorporation reflects both a parallel intent and parallel assumptions. Thus section 112 standards set to protect against adverse health effects characterized by a threshold must also be based solely on health,[16] with an "ample" rather than an "adequate" margin of safety to account for the greater severity of the pollutants involved.[17] The apparent underlying congressional assumption, however—the existence of thresholds—also leads the Administrator to believe, in the absence of significant contrary indications, that Congress did not specifically foresee or address the problems inherent in applying the margin of safety concept to air pollutants under fundamentally different circumstances.

(2) The carcinogen problem: no apparent thresholds. Regulation airborne carcinogens under section 112 does require the application of the margin of safety concept under fundamentally different circumstances. Although carcinogens, as air pollutants which may cause an increase in mortality, are clearly among the pollutants that the Administrator is required to regulate under section 112 of the Act, carcinogens must also (for the reasons discussed earlier) be regarded for public health purposes as having no identifiable adverse health effects thresholds. The method used to establish a margin of safety for a threshold pollutant—setting the standard somewhere below the demonstrated effects level at a point at which the absence of adverse health effects is predicted—therefore cannot be used to set standards (other than at zero) for carcinogens under section 112, since risk of cancer is believed to exist at any exposure level greater than zero.

In establishing margins of safety for carcinogens, therefore, the task is to determine how low the risk of the occurrence of cancer in an exposed persons or the projected incidence in an exposed population must be driven before a margin of safety can be considered ample to protect the public health. Only two approaches are available for performing this task: either the emission standards must be set at zero to eliminate the risk of cancer incidence altogether, or some residual risk must be permitted. Because Congress did not give specific consideration to this problem, the Administrator does not believe that section 112 expresses an intent to eliminate totally all risks from emissions of airborne carcinogens.[18] Section 112 standards which permit small residual risks can, in the Administrator's judgment, therefore provide an ample margin of safety to protect the public health.

(3) *The consequences of a zero-risk requirement.* This view is based on several additional factors. Foremost among these is the belief that if Congress had intended the drastic results that would flow from a requirement to eliminate all risk from emissions of carcinogens, it would have spoken with much greater clarity.[19]

A requirement that the risk from atmospheric carcinogen emissions be reduced to zero would produce massive social dislocations, given the pervasiveness of at least minimal levels of carcinogenic emissions in key American industries. Since few such industries could soon operate in compliance with zero-emission standards, closure would be the only legal alternative. Among the important activities affected would be the generation of electricity from either coal-burning or nuclear energy; the manufacturing of steel; the mining, smelting, or refining of virtually any mineral (*e.g.*, copper, iron, lead, zinc, and limestone); the manufacture of synthetic organic chemicals; and the refining, storage, or dispensing of any petroleum product.[20] That Congress had no clear intention of mandating such results seems self-evident.

The conclusion that Congress did not contemplate closure of the nation's basic industries, or even widespread industry closures, is also supported by the history and language of section 112. First, Congress in 1970 gave the subject of plant closures only brief consideration in connection with section 112.[21] While the legislative history makes clear that the Administrator is empowered to set standards under section 112 that result in plant or industry closures where appropriate,[22] it is by no means clear that Congress intended that result for all non-threshold hazardous pollutants, or even that Congress really focused on the problem.[23] Indeed, the very limited nature of the legislative history itself compels the conclusion that closure of the nation's basic industries, irrespective of the actual levels of risk involved, could not have been contemplated. That conclusion becomes even more inescapable in light of the 1977 Amendments, which added radioactive substances—long regarded as confirmed carcinogens and emitted from a wide variety of sources—to the coverage of the Act, with no mention anywhere of industry closures as the inevitable consequence.

The language of section 112 is also consistent with today's proposal. In using the phrase "margin of safety," Congress was borrowing a concept from the field of enginering,[24] where it had previously employed the term.[25] By prescribing the use of a margin of safety for the load factors of underground mine hoist cables in the 1969 Mine Safety Act, for example, Congress surely did not intend to suggest that the safety factor must guarantee a failure risk of zero. Indeed, no reputable engineer would say that even with a margin of safety an "adequately strong" hoist cable[26] presents a failure risk of absolutely zero.

Nor does the use of the term "safety" necessarily imply a zero-risk concept. Where Congress has intended to require safety from the risk of cancer to be absolute, it has known how to express that intention clearly, as it did in the Delaney Clause of the Food and Drug Act,[27] prohibiting the use of any food additive found to induce cancer in man or animal at any level of exposure. This provision was enacted years before section

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[13] Some physiological responses (not producing adverse health effects) may occur at exposure levels below the thresholds.

[14] S. Rep. No. 91-1196, 91st Cong., 2d Sess., at 9-10 (1970).

[15] *See, e.g.*, 44 FR 8202 (February 8, 1979) (revisions of ozone standard). Although Congress has precluded consideration of the feasibility of attaining NAAQS in the standard-setting process, it has provided various means for feasibility factors to be considered in connection with control of the pollutants described in section 108. Control of pollutants listed under section 108 can take account of feasibility through opportunities for allocation of the burdens of control by the states under section 110, through delays in compliance under sections 113(d) and 119, and through attainment date extensions under section 110(e). Under section 111(d) of the Act, feasibility is taken into account directly in connection with control of certain similar, but less ubiquitous, pollutants emitted by discrete source categories.

[16] This view was recently endorsed in *Hercules, Inc. v. EPA*, F.2d——, 12 ERC 1376 (D.C. Cir., 1978).

[17] This construction of the difference between "adequate" and "ample" was recently expressed by the U.S. Court of Appeals for the District of Columbia circuit in *EDF (PCBs) v. EPA*,——F.2d——, 12 ERC 1353 (1978).

[18] While Congress apparently believed that some substances might be so toxic that any level of emissons should be prohibited (*see, e.g., A Legislative History of the Clean Air Amendments of 1970*, U.S. Government Printing Office, 1974, at 227) (Statement of Senator Muskie), it seems to have had in mind sustances so poisonous that essentially any ambient concentration would be expected to produce widespread serious health effects, rather than substances with the characteristics of carcinogens, which would produce only scattered, random health effects at very low concentrations.

[19] *Cf. Brown* v. *EPA*, 521 F. 2d 827, 834 (9th Cir., 1975), *vacated on other grounds*, 431 U.S. 99 (1977), opinion on remand, 585 F. 2d 685 (1977).

[20] One widespread, though non-industrial, activity that would also be affected is the buring of wood in home fireplaces.

[21] *See, e.g., Legis. Hist., supra*, at 133 (statement of Senator Muskie).

[22] *See, Legis. Hist., supra*, at 133 (statement of Senator Muskie); *Adamo Wrecking Co.* v. *U.S.*, 434 U.S. 275, 54 L. Ed. 2d 538, 555 (Stevens, J., dissenting).

[23] In fact, the congressional expectation in 1970 was apparently that only a few pollutants would untimately be found "hazardous" within the meaning of what became section 112. See, S. Rep. No. 91-1196, *supra*, at 20.

[24] See *EDF (PCBs)* vs. *EPA*, *EPA*, *supra*, slip opin. at 40.

[25] Federal Coal Mine Health and Safety Act of 1969, 314(a), 30 U.S.C. § 874(a); *see also* 30 CFR 75.1401-1 (1977).

[26] 30 U.S.C. 874(a).

[27] 21 U.S.C. 346(c)(3)(A).

112, and the absence of comparable specificity in section 112 suggests that "an ample margin of safety to protect the public health" need not be interpreted as requiring the complete elimination of all risks.[28]

In interpreting the margin of safety concept in section 112 of the Clean Air Act, moreover, there is no reason to believe that Congress intended to make air pollution practically the sole facet of American life from which the government would attempt to eliminate risk entirely.

Not only is there no indication, as noted above, that Congress considered the inevitable consequences of such a decision, but such an interpretation would also be quite incongruous in view of the provisions of numerous other public health statutes enacted during or since 1970. These statutes deal-with, among other things, environmental carcinogens to which people are equally or more exposed, and they all permit consideration of factors other than risk in setting standards or taking comparable actions.[29]

In particular, the recent enactment of the Toxic Substances Control Act, which was intended to address the problem of toxic substances comprehensively, supports the view that where Congress has specifically considered the problem of reducing risks posed by environmental exposure to carcinogens, it has not required complete elimination of those risks. Taken together, the Administrator believes that these statutes provide strong evidence that the complete elimination of risk from environmental exposure to carcinogens is not the task with which he has been charged by Congress.

B. *Ample margins of safety under section 112.* For reasons stated previously, the Administrator has concluded that section 112 does not require him to base all emission standards for carcinogens on a criterion of zero risk from exposure to such substances. Once that proposition is accepted, at least limited consideration of factors other than the level of risk itself is unavoidable, since some criteria are needed in order to judge whether or not the degree of public health protection associated with a particular standard is "ample." [30]

The Administrator believes that section 112 clearly requires this determination to be based primarily on risk. The Administrator also believes, however, that he may consider other social and economic factors in determining whether an ample margin of safety is provided by a given control level. These factors include the benefits of the activity or substance producing risk; the distribution of the benefits versus the distribution of the risks; the availability and possible environmental risks of substitutes for that substance or activity; and the cost of reducing the risks further.

The rule proposed today will provide an ample margin of safety in several ways, consistent with this view. First, it protects against the unknown dangers of low-level exposures to airborne carcinogens by treating them as pollutants presenting risks even at low exposure levels. Next, it places primary emphasis on risk in establishing standards for sources regulated under section 112, and therefore requires at a minimum that such sources use best available technology to reduce cancer risks from their emissions. Beyond that, additional control measures will be required to eliminate residual risks judged unreasonable in light of the factors noted above. If necessary, this could entail closure of a source or even an industry, although the Administrator is not now aware of any source category whose carcinogenic emissions would be likely to require industry closure.

The proposal would also carry out the public health mandate of section 112 in two additional ways: first, by quickly imposing generic standards where possible to eliminate swiftly certain existing sources of carcinogenic emissions; and second, by applying the unreasonable risk criterion to contain the risks posed by emissions from new sources. The Administrator believes that provisions dealing specifically with the otherwise unpredictable increases in risks posed by emissions from new sources are a necessary element of a policy under section 112 that requires the elimination of unreasonable residual risks. The Administrator also regards these provisions as consistent with, if not required by, the policy of the Act to afford maximum public health protection b preventing significant increases in exposure to pollutants regulated by the Act.[31]

Finally, since the issues posed by today's proposal have not yet been judicially resolved,[32] the Administrator regards the foregoing analysis of the requirements of section 112 as a valid exercise of his discretion to interpret the meaning of these complex provisions of the Act.[33] The interpretation of section 112 stated here is the first detailed analysis the Administrator has published of the application of the section to regulation of airborne carcinogens. It is, however, consistent with his initial (and subsequent) actions in regulating asbestos, the first substance regulated under section 112 in part for carcinogenic effects. In that initial rulemaking, despite the absence of a known threshold level for carcinogenic effects, the Administrator explicitly considered the technological and economic importance of certain uses of asbestos and decided that, although a certain "minimal risk to the public" would probably remain, emissions from certain of those activities should be allowed to continue.[34]

EPA also considered such factors in establishing emission standards for vinyl chloride, the only other substance for which emission standards have been set under section 112 to control carcinogenic effects. The interpretations of section 112 published in connection with that action are consistent with, though not as detailed as, the analysis appearing here.[35] Those interpretations were reiterated, and the health-based nature of section 112 emphasized, in a proposal to amend the vinyl chloride standards.[36] These publications make clear the Administrator's consistent view that section 112 requires him to focus principally on health risks in regulating airborne carcinogens, but that it does not require the elimination of all risks from carcinogens in establishing an ample margin of safety to protect the public health.

References

1. Occupational Safety and Health Administration, Identification, Classification and Regulation to Toxic Substances Posing a Potential Occupational Carcinogenic Risk, 29 CFR Part 1990, 43 FR 54148, October 4, 1977.

2. Consumer Products Safety Commission, "Interim Policy and Procedure for Classifying, Evaluating, and Regulating Carcinogens in Consumer Products", 43 FR 25658, June 13, 1978. Withdrawn, 44 FR 23821, April 23, 1979.

3. "Petition for the Initiation of Rulemaking Proceedings to Establish a Policy Governing the Classification and Regulation of Carcinogenic Air Pollutants under the Clean Air Act," Environmental Defense Fund, November 7, 1977.

4. "Testimony on OSHA's Generic Carcinogen Proposal," American Industrial Health Council, New York.

5. EPA, "Health Risk and Economic Impact Assessments for Suspected Carcinogens', Interim Procedures and Guidelines, 41 FR 21402, May 25, 1976.

6. "Scientific Bases for Identification of Potential Carcinogens and Estimation of Risks" Report by the Work Group on Risk Assessment of the Interagency Regulatory Liaison Group (IRLG) 44 FR 39858, July 6, 1979.

7. EPA's Testimony on OSHA's Proposed Cancer Policy, presented at OSHA public hearings beginning May 16, 1978.

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[28] That Congress might have chosen an absolute safety rule for food additives, but not for air pollution, is quite plausible on policy grounds. *Cf.* Doniger, "Federal Regulations of Vinly Chloride," 4 *Ecology Law Quarterly* 497, at 656-658 (1978).

[29] *See,* Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 U.S.C. 136a *et seq.;* Toxic Substances Control Act, 15 U.S.C. 2601 *et seq.;* Safe Drinking Water Act, 42 U.S.C. 300f *et seq.;* Clean Water Act, as amended, 33 U.S.C. 1251 *et seq.;* and Occupational Safety and Health Act of 1970, 29 U.S.C. 651 *et seq.*

[30] As discussed above, this conclusion is of course limited to situations where standards cannot be set on the basis of an adverse health effects threshold. Where standards can be set on that basis under section 112, factors other than health effects need not and may not be considered.

[31] *See,* §§ 101(b)(2) and 160-169 of the Act, 42 U.S.C. 7401(b)(2) and 7470-7479, H.R. Rep. No. 95-294, 95th Cong., 1st Sess. at 103-178 (1977). The Administrator has previously expressed his view that new sources of carcinogen emissions should not be allowed to create significant new risks to exposed populations, 42 FR 28154, 28156 (June 2, 1977), and that new sources should be required to use improved emission control techniques, *Id.* at 28155.

[32] The Administrator does not regard the *EDF(PCBs)* and *Hercules* cases noted above as controlling precedent for the interpretation expressed here. Neither of those cases involved regulations promulgated under section 112, and neither dealt with the primary question involved here, the regulation of carcinogens—nonthreshold pollutants—under the Clean Air Act.

[33] *See, e.g., Train* v. *NRDC,* 420 U.S. 60 (1975).

[34] *See* 38 FR 8820 (April 6, 1973).

[35] *See* 40 FR 59532, 59534, 59535-59536 (December 24, 1975); 41 FR 46560, 46561-46562 (October 21, 1976).

[36] *See* 42 FR 28154 (June 2, 1977).

40 CFR Part 61

[FRL 1254-2]

National Emission Standards for Hazardous Air Pollutants; Advance Notice of Proposed Generic Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Advance notice of proposed rulemaking.

SUMMARY: This notice sets forth draft generic standards that EPA may propose for sources of carcinogenic organic chemicals that are listed as hazardous air pollutants under section 112 of the Clean Air Act. Elsewhere in this issue of the Federal Register EPA is proposing a policy for the identification, assessment and regulation of airborne carcinogens under section 112. Under this policy, EPA would employ generic standards where applicable to reduce emissions of airborne carcinogens. These generic standards would be proposed simultaneously with the listing of a carcinogen as a hazardous air pollutant. The intent of this notice is to solicit comment on the generic standards EPA is currently developing.

DATES: Written comments and information should be postmarked on or before December 10, 1979.

ADDRESSES:

Comments: Written comments and information should be submitted to the Central Docket Section (A-130), U.S. Environmental Protection Agency, Attn: Docket No. A-79-13, 401 M Street, SW., Washington, D.C. 20460.

Docket: Docket No. A-79-13, containing material relevant to this rulemaking, is located in the U.S. Environmental Protection Agency, Central Docket Section, Room 2903B, 401 M Street, SW., Washington, D.C. 20460. The docket may be inspected between 8:00 a.m. and 4:00 p.m. on workdays, and a reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: Environmental Protection Agency, Office of Air Quality Planning and Standards, Emission Standards and Engineering Division (MD-13), Research Triangle Park, North Carolina 27711, Attention: Mr. Don R. Goodwin, telephone number (919) 541-5271.

SUPPLEMENTARY INFORMATION: Section 112 of the Clean Air Act as amended, 42 U.S.C. 7412, requires EPA to regulate hazardous air pollutants by establishing emission standards and, where necessary, certain other measures to protect public health. The rapidly developing body of knowledge concerning toxicology indicates that many air pollutants, primarily in the form of airborne carcinogens, may present significant risks to public health. Many of these air pollutants will likely be volatile organic chemicals. The technical complexity and diversity of the organic chemical manufacturing industry and the stringency of Clean Air Act time limits on regulation of hazardous air pollutants indicate a need to improve EPA's regulatory procedures in this area. Accordingly, as a significant part of the program for regulation of airborne carcinogens contained in the rule proposed elsewhere in today's Federal Register, EPA is developing generic standards for use in reducing emissions of organic chemical carcinogens listed under section 112 in the future. The use of generic standards would provide a quick, first step in the regulation of organic chemical air carcinogens.

Generic Standards

Generic standards used to regulate emission sources of carcinogenic air pollutants are standards which are independent of process or chemical and are based on the similarity of operations and equipment throughout an industry, such as the organic chemical manufacturing industry. They can be applied to similar emission sources and represent reasonable and prudent measures a responsible plant owner or operator would take in dealing with a carcinogenic air pollutant.

Consistent with the mandate of section 112 that emissions of hazardous air pollutants be reduced quickly, generic standards would be proposed for applicable emission sources simultaneously with listing of a volatile organic chemical determined to be an airborne carcinogen. Depending on the nature of the listed organic chemical and the emission sources of this chemical, generic standards may require "tailoring" in certain cases to reflect unique or unusual situations. Generic standards and the rationale supporting those standards would be published in the Federal Register. Additional documents outlining and summarizing the information supporting the standards would not necessarily be published. However, supporting information would be available at the time of proposal for public inspection. This supporting information would include general assessments of the economic, energy, and environmental impacts of the proposed standards.

Proposal of generic standards for applicable organic chemical emission sources would be followed by a public comment period and an opportunity for a public hearing. EPA would evaluate the comments submitted during the public hearing and comment period, make appropriate changes to the proposed generic standards, and then promulgate the generic standards. Generic standards would be followed, in most cases, by proposal of additional standards. These additional standards would be developed under the rule proposed today for regulation of airborne carcinogens.

As EPA identifies and develops additional standards, an evaluation of the reasonableness of including these requirements in future generic standards will be made. As a result, the generic standards will evolve and become more extensive as EPA's experience and expertise increase.

Implementation of Generic Standards

As discussed below, the draft generic standards focus primarily on reducing fugitive emissions through the use of an effective leak detection and repair program. There are a number of possible approaches to implementing these generic standards. The first approach would be to require the attainment of specific performance levels by the sources regulated. For example to control fugitive emissions from pump seals, a performance level could specify that no more than a certain percentage of pump seals leak. Achievement of the performance level would be enforced through tests of pump seals in a plant to determine what percentage of seals were leaking. If more leaks were found than the percentage allowed by a performance level, the source would be out of compliance and enforcement action would be taken. This approach, therefore, would be similar to the approach followed in most existing new source performance standards and national emission standards for hazardous air pollutants. Because this approach would depend on testing, rigorous enforcement of the standards would be possible. This approach also would provide each plant with complete flexibility to institute its own method of achieving and maintaining compliance with the standards. Data to establish specific performance levels, however, is not currently available, although programs underway may provide some data which could be used for this purpose. If the data developed by these programs show that this approach is feasible, future generic standards may incorporate performance levels in some areas.

A second approach to implementing generic standards would be to specify that certain work practices be followed. For example, to control fugitive emissions from pump seals, the standards would specify (1) how often pump seals must be inspected for leaks,

(2) the detection technique and procedure for determining if a leak exists, and (3) the time period within which any leak found must be repaired. Compliance with work practice requirements would be enforced through examination of records kept by the plant showing that inspections were carried out, leaks detected, and repairs made. Compliance would be monitored through use of routine reporting. This approach would, of course, provide less flexibility to the plant owner or operator. The reliance of this approach on self-reporting and recordkeeping could make enforcing generic standards difficult. However, data and information are currently available which allow the development of work practice requirements.

A third approach to implementing generic standards would use the standards as guidelines. Guidelines would provide maximum flexibility in the actions by industry; each plant could tailor its method of locating and repairing leaks to its particular situation. Guidelines would also allow innovation in control techniques. Guidelines, however, would have no legal status. Therefore, EPA could not enforce compliance with guidelines. Given the nature of the problem presented by public exposure to hazardous air pollutants and the requirements of section 112, this approach is inadequate.

The Manufacturing Chemists Association (MCA) has suggested an approach similar to that of guidelines. MCA's approach would require owners and operators to prepare and implement plant-specific plans for reducing fugitive emissions of the hazardous air pollutant. The draft generic standards would serve as guidelines for developing these plans. Plans could depart from the guidelines if an owner or operator felt the departure was justified.

MCA's suggested approach is similar to an approach used by EPA in oil pollution prevention regulation (40 CFR Part 112) promulgated in 1973 and in hazardous substance pollution prevention regulation (40 CFR Part 151) proposed in 1978 under the Clean Water Act. This approach provides each plant with flexibility and allows innovation in control techniques. In the proposal, enforcement of this approach is triggered by an identifiable event, such as discharge of hazardous substances in harmful quantities as determined in 40 CFR Part 118, and focuses on a review of the effectiveness of the plan. Enforcement of this approach is enhanced by surprise inspections which focus on review of the plan. After review of a plan, an owner or operator may be required to amend the plan. Also, the owner or operator is liable for a civil penalty for violations of requirements of the regulation.

The plan preparation approach, if used to implement generic standards, would be enforced through review of a plan to determine the effectiveness of the plan. Review of each plan would be required at some point in time. The mechanism for triggering review could be based on an identifiable event or could be based on an automatic or periodic review.

In the example of the proposed regulation under the Clean Water Act, review is triggered by an identifiable event, such as a discharge. For emission sources covered by the draft generic standards, an identifiable event to trigger review of a plan is not readily apparent. These emission sources are spread out in an organic chemical plant and often require a measurement device for detection. A mechanism for triggering review other than the identifiable event mechanism would be necessary.

Another mechanism for triggering of review plans would follow procedures similar to those used under 40 CFR Part 51 for development of State Implementation Plans. These procedures would require automatic preparation of plans and their submittal to EPA for review. After a review to determine the effectiveness of a plan, the plan would be approved or disapproved. Approved plans would be incorporated into 40 CFR Part 61, thus assuring their implementation and allowing their enforcement. Incorporating plans into 40 CFR Part 61 would be very time consuming. The time and resources required to review and determine the effectivieness of a plan and then to incorporate the plan into 40 CFR Part 61 prohibit the use of this mechanism.

Review of a plan to determine its effectiveness is central to enforcement of the plan proparation approach. The use of an identifiable event to trigger review of a plan does not appear reasonable. The use of automatic review procedures similar to those used under 40 CFR Part 51 is prohibited by the time and resources required by the procedures. Thus, the plan preparation approach is limited in its usefulness.

EPA recognizes the general desirability of the performance level approach to generic standards. However, data and information are not available to develop these types of generic standards at the present time. Although EPA recognizes the possible use of the plan preparation approach, the time and resources required to establish effective plans prohibit the usefulness of this approach. Therefore, in developing draft generic standards, EPA has chosen the approach of specifying detailed work procedures as the most viable approach now available. This is consistent with EPA control techniques guidelines documents which recommend this approach. EPA invites public comment on advantages and disadvantages of each of the approaches discusesed above.

Draft Generic Standards

The draft generic standards are outlined in Attachment A to this notice. These draft standards would be proposed for sources of carcinogenic organic chemicals listed under section 112 of the Clean Air Act. When proposing generic standards for regulation of carcinogenic organic hazardous air pollutants, EPA would evaluate the appropriateness of each standard outlined in Attachment A. Tailoring may be required and therefore in some instances, additions to these draft standards may be made, and in other instances, deletions may be made.

To achieve the goal of expeditious control of carcinogenic emission sources, the draft generic standards were based on the following selection criteria. First, draft generic standards were selected which are broadly applicable to organic chemical emission sources. Second, standards were selected which lend themselves to quick implementation and third, standards were selected which do not require substantial capital expenditure. Finally, standards were selected which would be consistent with any additional standards promulgated later; thus, the generic standards could be instituted with confidence.

The draft generic standards categorize emission sources of organic chemicals into six groups. These groups are: fugitive emissions, chemical storage, chemical transfer and handling, waste disposal, process vents, and air pollution control devices. All of these emission sources lend themselves to control through the use of generic standards. In accordance with the selection criteria, the draft generic standards would require control of these emission sources, for the most part, through the use of improved operation, maintenance, and housekeeping practices.

The major focus of the draft generic standards is leak detection and repair. The draft standards would require inspection of potential fugitive emission sources at specific intervals to locate leaks which require repair. These fugitive emission sources consist of equipment which comes into contact

with any liquid or gaseous mixture containing more than a specified minimum concentration of the listed pollutant. Inspection includes routinely monitoring potential fugitive emission sources to detect gaseous leaks, and routinely observing sources to detect liquid leaks. If an organic chemical concentration greater than a defined action level is measured at the interface between the source and the atmosphere using a portable detection device, it is considered that a gaseous leak has been detected. Upon monitoring, if a gaseous leak is detected, the leak must be repaired within a specified repair interval. Upon observation, if a liquid leak is detected, the emission source is monitored. If a gaseous leak is detected, then repair is required within the specified repair interval. Repair of the leak would be confirmed by monitoring the source to determine that the concentration is less than the defined action level. Inspection intervals ranging from weekly to annually are currently being considered. Values of 1 to 10 percent for the minimum concentration in the mixture, 5 to 15 days for the repair interval, and 1,000 to 10,000 parts per million by volume measured as hexane (ppmv) as the action level or definition of a leak are also currently being considered.

If repair of a leak would result in more emissions than cumulative emissions from the leak prior to a scheduled process or operation shutdown, or if repair of a leak is not possible because of location, service, or unavoidable circumstances, the required repair could be delayed pending approval of EPA. EPA Regional Enforcement Divisions must be notifed by telegram or telephone within a specified number of days of requests for delay in the repair of a leak, and would retain the authority to disapprove any requests. If, however, EPA failed to respond within a specified number of days to a request for delay in repair of a leak, approval of the request would be granted automatically. Values of 2 to 5 days from the finding of a leak for requesting of a delay, and 2 to 5 days from receiving of a delay request for EPA response to the request, are being considered. Rather than follow this procedure for all leaks, EPA is considering this reporting procedure only for requests for delays in repair of excessive leaks. An excessive leak would be defined as some emission concentration greater than the current 1,000 to 10,000 ppmv range being considered as the definition of a leak. For example, an excessive leak could be defined as a concentration of equal to or greater than 100,000 ppm. Because either of these approaches is likely to require excessive resources and may be difficult to enforce, EPA is requesting comment on their feasibility and alternative approaches which could be employed.

The numerical values of the specific requirements in the draft generic standards were based on preliminary evaluation of various engineering studies. In most cases, the requirements are illustrated by a range of values that are being considered. The inspection intervals, which could vary from weekly to annually for equipment in liquid service and from monthly to quarterly for equipment in gaseous service, were based on data developed from test programs conducted within refinery and petrochemical plants. In general, the inspection intervals are based on the observed frequency of leaks and their expected emission rates. Preliminary evaluation of fugitive emission sources within benzene production units of petroleum refineries indicates that the inspection interval influences potential emission reduction more than other factors, such as definition of a leak, or repair interval. Currently, a monthly inspection interval for equipment in gaseous and liquid service appears the most reasonable inspection interval.

The repair interval which ranges from 5 to 15 days was based on observations in the petroleum refinery and petrochemical industry and on expected reporting requirements. In many cases, repairs could be made sooner than 5 days. However, there are unavoidable circumstances which can delay repair beyond 5 days. Circumstances, such as a plant's parts stock being depleted, are generally avoidable. While a plant normally stocks sufficient spare parts, there may be unique circumstances leading to the depletion of a plant's parts stock. Requests for delays in repair of leaks will be approved only where repair is likely to result in emissions in excess of the emissions resulting from the leak, or where repair is not possible because of circumstances which EPA considers unavoidable. Thus, the objective in selecting the repair interval was to select a time interval consistent with the ability of a plant to repair a leak expeditiously, but not to select a time interval so short that it requires plants to continually request repair delays for repair of routine leaks. Preliminary evaluation of fugitive emission sources within benzene production units of petroleum refineries indicates that the emission reduction gained by going from 15 to five days is small. Thus, the 15-day repair interval is currently considered reasonable.

The purpose of specifying a minimum concentration level of the pollutant in gaseous or liquid mixtures is to exclude process streams with trace quantities of the hazardous pollutant. The 10 percent upper boundary for this concentration level is based on analogy with the current vinyl chloride national emission standard. The lower boundary of 1 percent is based on estimates that this level, under certain conditions, would allow emissions of less than 10 ppmv of the hazardous air pollutant. Preliminary evaluation of fugitive emission sources within benzene production units of petroleum refineries indicates that the 10 percent minimum concentration level is most reasonable. Going from 10 percent to 1 percent would greatly increase the number of sources covered by the standards without a corresponding reduction in emissions. Therefore, 10 percent is currently considered the most reasonable minimum concentration level.

A hexane-based definition of a gaseous leak at 10,000 ppmv as defined in an EPA control techniques guideline document, "Control of Volatile Organic Compound Leaks from Petroleum Refinery Equipment" (EPA–450/2–78–036), was considered the maximum for use in regulating organic hazardous air pollutants. The 1000 ppmv definition of a leak is a simple reduction of the value in the control techniques guideline. The 1000 ppmv value appears a reasonable lower value because some leakage is unavoidable for emission sources covered by the draft generic standards. The 10,000 ppmv and 1000 ppmv concentrations would be measured at the interface between the leak and the atmosphere. These values are based on a technical evaluation of leaks and are not based on an evaluation of potential health risk of leaks. Preliminary evaluation of fugitive emission sources within benzene production units of petroleum refineries indicates that the 10,000 ppmv action level is more reasonable than the 1000 ppmv action level. Experience indicates that repair of leaks will result in emission reduction with an action level of 10,000 ppmv. However, experience does not indicate that repair of leaks with concentrations between 10,000 and 1000 ppmv will result in emission reduction. Therefore, 10,000 ppm is currently considered the most reasonable action level.

Miscellaneous Issues

Continuous area-wide monitoring to measure ambient concentrations of specific hazardous organic compounds was considered. EPA experience with the effectiveness of area-wide monitoring indicates that this technique

is not as effective in locating leaks as a seal-by-seal inspection, which is the technique outlined in the draft generic standards. The use of area-wide monitoring may add to the effectiveness of seal-by-seal inspection, but experience indicates that this added effectiveness in minimal. Also, area-wide monitoring is a capital intensive technique. Thus, continuous area-wide monitoring seems impractical for the draft generic standards.

On the other hand, some organic chemical facilities currently have leak detection and repair programs based on continuous area-wide monitoring of ambient air hydrocarbon concentrations. In some cases, these programs or other types of leak detection and repair programs might be as effective in reducing fugitive emissions as the program described in the draft generic standards. During meetings with industry associations, it has been suggested that an alternative to requiring duplication of equally effective leak detection and repair programs should be developed. This suggestion is reasonable. However, it depends upon determining equivalency of various programs with the draft generic standards. Three basic criteria seem necessary for any technique for determining equivalency. These criteria are: (1) the technique for determining equivalency should minimize both industry and Agency resource requirements; (2) the type of data necessary to demonstrate equivalency should normally be available or easily developed; and (3) the technique should be quantitative, with little room for discretion or argument concerning equivalency. EPA specifically invites comments on possible approaches to determining equivalency that meet these criteria.

The draft generic standards also include requirements for recordkeeping and reporting. Recordkeeping and reporting are considered necessary to insure that the improved operation, maintenance, and good housekeeping practices generally required by the draft generic standards are put into practice quickly, effectively, and consistently. Detected leaks would be recorded in a log and the corrective actions noted when a leak is repaired. EPA would be notified on a quarterly basis of leaks not repaired within the specified repair interval; these quarterly reports would include a listing of those units and components which leaked past the specified repair interval, date and duration of these leaks, and concentrations of the hazardous organic chemicals. In some cases, recordkeeping and reporting would be a duplication of other EPA requirements. Where duplication is unnecessary, duplication would not be required in the generic standards.

In early versions of the draft generic standards, recordkeeping and reporting requirements were the only measures used to ascertain compliance with the standards. In meetings with environmental groups, it was suggested that either EPA or a certified independent contractor perform scheduled inspections, observations and monitoring to confirm compliance with the standards. This suggestion would be extremely burdensome on EPA resources. Therefore, it has not been included in the draft generic standards. This suggestion, however, did lead to incorporation of an approach requiring the plant's owner or operator to notify EPA one week prior to the date of certain inspections, observations and monitoring. This would give EPA the opportunity to observe these activities and determine compliance with the generic standards, without requiring extensive resource commitments. EPA is actively seeking specific comments on this approach to enforcement of the draft generic standards, and specific comments on alternative approaches.

Minimal capital expenditure was a criterion for selection of the draft generic standards. The most readily identifiable capital expenditure required by the draft standards is the purchase of the portable organic vapor monitor. The cost of two such monitors used by EPA totals about $10,000. A preliminary estimate of annual leak detection and repair costs for benzene production units within a petroleum refinery is about $25,000 per year. This estimate includes the amortized cost of two monitors, annual operating cost of the monitors, annual cost of labor for leak detection, annual parts and labor cost for leak repair, and annual cost of administrative support. It does not, however, include cost savings, which could be significant, for the value of the retained organic chemicals. EPA is interested in specific information on the cost of the draft generic standards.

The draft standards would also require the owner or operator to submit to EPA within four months following the promulgation of a specific generic standard an estimate of emissions of the hazardous air pollutant. This estimate would be based on nameplate operating capacity and would be categorized by emission source.

Specific Requests

EPA is requesting comments on the approaches discussed under the implementation of Generic Standards section of this preamble. EPA is interested in comment on other approaches for implementing generic standards and is specifically interested in any data and information which could lead to the development of performance level generic standards and means for enforcing the plan preparation approach advocated by MCA.

EPA is also interested in specific comments on the following aspects of the draft generic standards: (1) identification of various operations, procedures and equipment that are sources of emissions of organic chemicals; (2) identification of demonstrated control techniques which can be broadly applied to these sources of emissions; (3) costs associated with the requirements listed in the draft generic standards; (4) standard equipment, designs, or operating and maintenance procedures (including periods of start-up and shutdown) for controlling emissions from operations that may emit organic chemicals; (5) comments on the various numerical ranges included in the draft generic standards; (6) comments on the approach of requiring requests for delays in repair of leaks or requests for delays in repair of excessive leaks only, and the specified levels of an excessive leak; (7) identification of techniques or procedures which could be used to determine the equivalency of alternative leak detection and repair programs; (8) identification of ways to reduce the burden of recordkeeping and reporting on the source and EPA while maintaining the effectiveness of the draft generic standards; (9) the enforcement approach of the draft generic standards and alternative approaches to the enforcement of these standards; and (10) specific information on leak detection and repair programs similar to the program in the draft generic standard; for each program, the information should include (a) chemical name and the process used to produce the chemical, (b) a detailed description of the leak detection and repair program, (c) the number of pieces of each type of equipment affected by the program, (d) separate costs for monitoring, equipment, installation of equipment, labor for monitoring, repair parts, labor for repair, and overhead, and (e) an estimate of the emission reduction potential and the product recovery credits, including an explanation of the estimation method.

This advance notice of proposed rulemaking is issued under the authority of sections 112, 114, and 301(a) of the

Clean Air Act as amended [42 U.S.C. 7412, 7414 and 7601(a)].

Dated: August 22, 1979.

Douglas M. Costle,

Administrator.

Attachment A—Draft Generic Standards

I. Applicability

Except as noted below, these standards would apply, for applicable emission sources, to the owner or operator of equipment affected by these standards. These standards would affect equipment which comes into contact with a liquid mixture containing 1 [10] percent or more by weight, or a gaseous mixture containing 1 [10] percent or more by volume, of organic chemicals listed by EPA as carcinogenic hazardous air pollutants under § 112 of the Clean Air Act.

Note.—Some requirements are illustrated with one end of the range of values currently being considered placed in brackets.

II. Fugitive Emissions

(A) All compressor seals and pipeline valves in gaseous service shall be monitored as provided in section IX (A) quarterly [monthly]. Whenever a concentration of 1,000 ppmv (parts per million by volume as hexane) [10,000 ppmv] is detected, a leak exists. Whenever a leak exists, it shall be repaired within 5 [15] days, except as provided in sections II (F) and (G).

(B) All pump seals, pipeline valves in liquid service, and process drains shall be monitored as provided in section IX (A) annually [monthly]. Whenever a concentration of 1,000 ppmv [10,000 ppmv] is detected, a leak exists. Whenever a leak exists, it shall be repaired within 5 [15] days, except as provided in sections II (F) and (G).

(C) Pressure relief valves, except those vented to a control device, shall be monitored as provided in section IX (A) quarterly [monthly]. Whenever a concentration of 1,000 ppmv [10,000 ppmv] is detected, a leak exists. Whenever a leak exists, it shall be repaired within 5 [15] days, except as provided in sections II (F) and (G).

(D) Whenever a rupture disk installed ahead of a pressure relief valve ruptures, it shall be replaced within 5 [15] days.

(E) Pump seals shall be observed for liquid leaks weekly as provided in section IX (B). Whenever liquids are observed running or dripping from a pump seal, the seal shall be monitored as provided in section IX (A). Whenever a concentration of 1,000 ppmv [10,000 ppmv] is detected, a leak exists. Whenever a leak exists, it shall be repaired within 5 [15] days, except as provided in sections II (F) and (G).

(F) When repair would clearly result in emissions in excess of the emissions resulting from the leak, repair may be delayed, as provided in section VIII (G), until a regularly scheduled shutdown. In determining whether emissions from repair of a leak would exceed those resulting from the leak, cumulative emissions over the time until the regularly scheduled shutdown shall be considered.

(G) Where repair is not possible because of location, service, or unavoidable circumstances, repair may be delayed, as provided in section VIII (G), until a time when repair is possible.

(H) Housekeeping practices.

(1) All liquid spills shall be cleaned up within 8 [24] hours. Acceptable cleanup methods include siphoning into a storage container (e.g., a portable spill tank), chemical absorption and other appropriate methods. Cleanup methods shall be in compliance with requirements under 40 CFR Part 151 (proposed).

(2) Wherever a valve is located at the end of a pipe or line, the pipe or line shall be sealed with a second valve, blind flange, plug or cap. This requirement does not apply to pressure relief valves.

(3) Whenever liquid or gaseous samples are taken from lines or equipment, a closeable container shall be used and sample valves shall be closed between samples. Liquid and gas that is bled from sample lines shall also be collected. All sample and bled material shall be returned to the process or disposed as provided in section V.

III. Chemical Storage

For storage equipment of greater than 40 [150] cubic meters capacity:

(A) All fixed-roof storage vessels exposed to direct sunlight shall be painted white. No more than 20 percent of the surface of the storage vessel, or 20 square meters, whichever is less, shall be covered with writing and figures. This requirement shall not apply to insulated, pressurized, or controlled temperature storage vessels and storage vessels equipped with a refrigerated condenser, carbon adsorber, incinerator, or any combination of these.

(B) Tank connection flanges and manway seals shall be monitored as provided in section IX (A) quarterly [monthly]. Whenever a concentration of 1,000 ppmv [10,000 ppmv] is detected, a leak exists. Whenever a leak exists, it shall be repaired within 5 [15] days, except as provided in sections II (F) and (G).

(C) Conservation vents on fixed roof storage vessels shall be inspected and, if necessary, maintained quarterly [monthly].

(D) Seals on floating roof storage vessels shall be inspected and, if necessary, maintained quarterly [monthly].

IV. Chemical Transfer and Handling

For equipment used in transferring and handling to or from rail cars, tank trucks, barges, and other transfer or transportation vehicles, all seals and fittings, excluding flanges, shall be monitored as provided in section IX (A) quarterly [monthly]. Whenever a concentration of 1000 ppmv [10,000 ppmv] is detected, a leak exists. Whenever a leak exists, it shall be repaired within 5 [15] days, except as provided in sections II (F) and (G).

V. Waste

(A) For waste covered by regulation under the Resource Conservation and Recovery Act (RCRA) and containing greater than 1 [10] percent by weight of a pollutant affected by section I, the following requirements would apply:

(1) Waste from sampling shall be disposed by returning it to the process stream, by reducing it in an appropriate air pollution control device, or by absorbing or adsorbing it with a liquid or solid. These absorbents and adsorbents, except those returned to the process stream, shall then be wastes.

(2) Waste shall be stored in vapor-tight containers.

(3) A Regional Administrator may require an owner/operator, who is demonstrating that treatment or disposal of a volatile waste (i.e., greater than 78 mm Hg) will not contribute airborne contaminant to the atmosphere, as provided in the NOTE in 40 CFR 250.45 (proposed), to demonstrate that treatment or disposal of the pollutant affected by section I will not contribute the airborne contaminant to the atmosphere such that concentrations above the source have the potential to increase risk to the public.

(B) For waste containing greater than 1 [10] percent by weight of a pollutant affected by section I and not covered by regulation under RCRA, the following requirements would apply:

(1) Disposal and treatment of waste shall be in compliance with standards for treatment/disposal, as provided in 40 CFR 250.45 (proposed).

(2) Disposal and treatment of waste shall be in compliance with sections V(A) (1), (2), and (3).

VI. Process Vents

Where a process vent may emit a hazardous organic chemical or any mixture containing 1 [10] percent or more by volume of hazardous chemicals, procedures describing process operation, including start-up, shutdown, normal and emergency procedures, shall be written and available to appropriate process operators. Operators shall receive an annual minimum of two hours of training in these procedures.

VII. Air Pollution Control Devices

Where a control device is used to reduce air pollutant emissions of a hazardous organic chemical, procedures outlining normal and emergency procedures for the control device shall be written and available to all operators. These procedures shall include at least all operating and maintenance procedures recommended by the control device manufacturer. Operators shall receive an annual minimum of two hours of training in these procedures.

VIII. Recordkeeping and Reports

(A) When a leak is detected, the presence of the leak shall be noted on a survey log as illustrated in Figure 1. Other information as shown shall be included on this survey log. Figure 1 is used to illustrate the minimum acceptable information to be recorded and is not a required form. A weatherproof and readily visible tag bearing an identification number and the date that the leak was detected shall be affixed to the leaking component. After the leak has been repaired, the remaining portion of the survey log shall be completed and the tag discarded. The survey log shall be retained for at least two years after the repair is completed.

(B) Quarterly reports shall be submitted to the appropriate EPA Regional Office, Enforcement Division Director. Each report shall include a list as shown in Figure 2 of all leaks that were located since the last report and not repaired within 5 [15] days. Each report shall include a separate list as shown

in Figure 2 of all leaks which were reported in a previous quarterly report and which have not been repaired. In addition, each report shall include a statement signed by the plant manager confirming that all weekly, [monthly], quarterly and annually inspecting, observing and monitoring has been performed.

(C) When a spill occurs, records of the date and the time of the spill and the cleanup shall be maintained for a minimum of two years. The records shall include an estimate of the quantity of the lost material, concentration of hazardous organic chemical, actions taken for the cleanup, and method of final disposal.

(D) When an owner or operator must comply with requirements in section VI, records of the times and approximate duration of all safety valve discharges shall be maintained for a minimum of two years. A summary of these safety valve discharges shall be reported annually to the appropriate EPA Regional Office, Enforcement Division Director.

(E) Written operating procedures as described in sections VI and VII shall be maintained and updated as necessary.

(F) Within four months of the date of promulgation of this section, the owner or operator of any facility subject to this section shall submit to the Administrator an evaluation of the emissions from the sources of the hazardous pollutant specified in this paragraph. This evaluation shall be an engineering estimate and shall be subject to the approval of the Administrator. The evaluation shall include as a basis the nameplate production rate, include the appropriate operating production rate, provide estimation of mass emissions from the sources in sections, II, III, IV, V, VI, and VII, and explain the technique for the estimation.

(G) A request for delay in repairing a leak must begin within two [five] days after locating the leak. The owner or operator making a delay request shall provide by telephone or telegram all necessary information for making an evaluation at the time of the initial request to the appropriate EPA Regional Office, Enforcement Division Director, and as required by the EPA Regional Office. In evaluating the request, the EPA Regional Office will consider the expected length of the delay, the reasons for the delay, the consequences of no delay, and other relevant factors. If the EPA Regional Office does not deny a requested delay within two [five] days after receipt of the request, the delay request will be granted automatically.

(H) Whenever an owner or operator is unable to comply with the two [five]-day requirement as provided in section VIII (G), he shall notify by telephone or telegram the appropriate EPA Regional Office, Enforcement Division Director, within one working day after determining the inability to comply. When notifying the appropriate EPA Regional Office, the owner or operator shall provide an explanation of the inability to comply with section VIII (G). In evaluating the inability to comply with section VIII (G), the EPA Regional Office shall consider the reasons for the inability to comply. After evaluation, the EPA Regional Office may allow application of section VIII (G) for delay requests after two [five] days after the plant locates a leak.

(I) At least one working week prior to each [monthly], quarterly, or annual inspections, observations, and monitoring, an owner or operator shall notify the appropriate EPA Regional Office, Enforcement Division Director, by telephone or telegram that such inspections, observations, or monitoring are scheduled.

IX. Test Methods

(A) Monitoring hazardous organic chemicals emissions.

This test method describes the procedures used to detect volatile organic chemical (VOC) leaks from sources of hazardous air pollutants. A portable test device is used to survey individual equipment leak sources. The specifications and performance criteria for the test instrument are included.

(1) Apparatus.

(a) Monitoring Instrument.

The VOC detection instrument used in this procedure may be of any type that is designed to respond to total hydrocarbons. The instrument must incorporate appropriate range options so that source levels can be measured. The instrument will be equipped with a pump so that a continuous sample is provided to the detector. The instrument meter readout will be such that the scale can be read to ±5 percent at 1,000 ppmv [10,000 ppmv]. The instrument must be capable of achieving the performance criteria given in Table 1. The definitions and evaluation procedures for each parameter are given in subcategory (3).

Table 1.—*Monitoring Instrument Performance Criteria*

Parameter	Specification
1. Zero drift (2-hour)	≤ 5 ppmv.
2. Calibration drift (2-hour)	≤ 5% of the calibration gas value.
3. Calibration error	≤ 5% of the calibration gas value.
4. Response time	≤ 5 seconds.

The instrument must be subjected to the performance evaluation test prior to being placed in service and every three months thereafter.

The performance evaluation test is also required after any modification or replacement of the instrument detector.

(b) Calibration Gases.

The VOC detection instrument is calibrated so that the meter readout is in terms of ppmv hexane. The calibration gases require for monitoring and instrument performance evaluation are a zero gas (air, <3 ppmv hexane) and a hexane in air mixture of about 1,000 ppmv [10,000 ppmv]. If cylinder calibration gas mixtures are used, they must be analyzed and certified by the manufacturer to be within ±2 percent accuracy. Calibration gases may be prepared by the user according to any accepted gaseous standards preparation procedure that will yield a mixture accurate to within ±2 percent. Alternative calibration gas species may be used in place of hexane if a relative response factor for each instrument is determined so that calibrations with the alternative species may be expressed as hexane equivalents on the meter readout.

(2) Procedures.

(a) Calibration.

Assemble and start up the VOC analyzer according to the manufacturer's instructions. After the appropriate warm-up period and zero or internal calibration procedure, introduce the 1,000 ppmv [10,000 ppmv] hexane or hexane equivalent calibration gas into the instrument sample probe. Adjust the instrument meter readout to correspond to the calibration gas value.

(b) Individual Source Surveys.

Place the instrument sample probe inlet at the surface of the component interface where leakage could occur. During sample collection, the probe should be moved along the interface surface with special emphasis placed on positioning the probe inlet at the local upwind and downwind side of the component interface. This general technique is applied to specific types of equipment leak sources as follows:

(i) Valves—The most common source of leaks from block (glove, plug, gate, ball, etc.) and control valves is at the seal between the stem and housing. The probe should placed at the interface where the stem exits the seal and sampling should be conducted on all sides of the stem. For valves where the housing is a multipart assembly, or where leaks can occur from points other than the stem seal, these sources should also be surveyed with the probe inlet moved along the surface of the interface.

(ii) Flanges and other connections—For welded flanges, the probe should be placed at the outer edge of the flange-gasket interface and samples collected around the circumference of the flange. For other types of non-permanent joints such as threaded connections, a similar traverse is conducted at the component interface.

(iii) Pumps and compressors—A circumferential traverse is conducted at the outer surface of the pump or compressor shaft and housing seal interface. In cases where the instrument probe cannot be placed in contact with a rotating shaft, the probe inlet must be placed within one centimeter of the shaft-seal interface. In those cases where the housing configuration of the pump or compressor prevents the complete traversing of the seal periphery, all accessible portions of the shaft seal should be probed. All other joints where leakage could occur will

also be sampled with the probe inlet placed at the surface interface. For pumps or compressors using sealing oil, the vent from the seal oil reservoir will be sampled by placing the probe inlet at approximately the centroid of the vent area to atmosphere.

(iv) Pressure relief devices—The physical configuration of most pressure relief devices prevents sampling at the sealing surface interface. However, most devices are equipped with an enclosed extension, or horn. For this type device, the probe inlet is placed at approximately the centroid of the exhaust area to atmosphere.

(v) Process drains—For open process drains, the sample probe inlet will be placed at approximately the centroid of the area open to the atmosphere. For covered drains, the probe should be placed at the surface of the cover interface and a circumferential traverse shall be conducted.

(3) Instrument performance evaluation procedures.

(a) Definitions.

Zero Drift—The change in the instrument meter readout over a stated period of time of normal continuous operation when the VOC concentration at the time of measurement is zero.

Calibration Drift—The change in the instrument meter readout over a stated period of time of normal continuous operation when the VOC concentration at the time of measurement is the same known upscale value.

Calibration Error—The difference between the VOC concentration indicated by the meter readout and the known concentration of a test gas mixture.

Response Time—The time interval from a step change in VOC concentration at the input of the sampling system to the time at which 95 percent of the corresponding final value is reached as displayed on the instrument readout meter.

(b) Evaluation Procedures.

At the beginning of the instrument performance evaluation test, assemble and start up the instrument according to the manufacturer's instructions for recommended warmup period and preliminary adjustments.

(i) Zero and calibration drift test—Calibrate the instrument per the manufacturer's instructions using zero gas and a calibration gas representing about 1,000 ppmv [10,000 ppmv]. Record the time, zero, and calibration gas readings (example data sheet shown in Figure 3). After 2 hours of continuous operation, introduce zero and calibration gases to the instrument. Record the zero and calibration gas meter readings. Repeat for three additional 2-hour periods.

(ii) Calibration error test—Make a total of nine measurements by alternately using zero gas and a calibration gas mixture corresponding to about 1,000 ppmv [10,000 ppmv]. Record the meter readings (example data sheet shown in Figure 4).

(iii) Response time test procedure—Introduce zero gas into the instrument sample probe. When the meter reading has stabilized, switch quickly to the 1,000 ppmv [10,000 ppmv] calibration gas. Measure the time from concentration switching to 95 percent of final stable reading. Perform this test sequence three (3) times and record the results (example data sheet given in Figure 5).

(iv) The calibration error test and the response time test may be performed during the zero and calibration drift test.

(c) Performance Calculations.

All results are expressed as mean values, calculated by:

$$\bar{x} = \frac{1}{n} \sum_{i=1}^{n} Xi$$

where:

Xi = value of the measurements
Σ = sum of the individual values
x = mean value (the absolute value of the mean value)
n = number of data points

The specific calculations for each performance parameter are indicated on the respective example data sheet given in Figures 3, 4, and 5. The example data sheets are constructed so that performance criteria tests can be conducted on 1,000 ppmv [10,000 ppmv] levels of gas.

(B) Observing for liquid leaks of hazardous organic chemicals.

This test method describes the procedures used to detect organic chemical liquid leaks from sources of hazardous air pollutants. The method uses visual observations to determine the existence of a liquid leak.

(1) Apparatus.

No apparatus is needed to perform this method.

(2) Procedure.

Observing from vantage points to sufficiently inspect the source, determine if any chemicals are leaking. A liquid leak exists if any chemical liquid is observed running or dripping from the surface of the source. When a chemical liquid is dripping to a surface which is in the vicinity of a possible hazardous pollutant emission source, locate the source of the liquid.

BILLING CODE 6560-01-M

Leak Detection and Repair Survey Log

Instrument Operator:_____

Recorder:_____

TAG NUMBER	UNIT	COMPONENT	HAZARDOUS ORGANIC CHEMICAL CONCENTRATION IN STREAM	DATE LEAK LOCATED	DATE MAINTENANCE PERFORMED	COMPONENT RECHECK AFTER MAINTENANCE	
						DATE	INSTRUMENT READING (PPM)
			DRAFT				

FIGURE 1. Example Monitoring Survey Log Sheet.

TAG NUMBER	UNIT	COMPONENT	HAZARDOUS ORGANIC CHEMICAL CONCENTRATION IN STREAM	DATE LEAK LOCATED	DATE MAINTENANCE PERFORMED	DATES MAINTENANCE ATTEMPTED	REASONS REPAIRS POSTPONED OR FAILED
			DRAFT				

FIGURE 2. Example Leak Report.

Instrument ID: _____ Calibration Gas Data: _____ ppmv

Date and Time	Zero Reading ppmv	Zero Drift ppmv	Calibration Gas Reading ppmv	Calibration Drift ppmv
Start				
1.				
2.				
3.				
4.				

Mean (1) Value: Zero Drift = _____ ppmv

Calibration Drift = $\frac{\text{mean calibration drift}}{\text{calibration gas value}}$ x 100 = _____%

(1) Absolute Value

Figure 3. Zero and Calibration Drift Determination

Instrument ID _____

Calibration Gas Mixture Data

_____ppmv

Run No.	Calibration Gas Concentration, ppmv	Instrument Meter Reading, ppmv	Difference,(1) ppmv
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			

Mean Difference(2) _____

Calibration Error = $\frac{\text{Mean Difference}^{(2)}}{\text{Calibration Gas Concentration}}$ = _____

(1) (Calibration Gas Concentration - Instrument Reading)
(2) Absolute Value

Figure 4. Calibration Error Determination

Instrument ID _____

Calibration Gas Concentration _____ppmv

95% Response Time:

1. _____Seconds
2. _____Seconds
3. _____Seconds

Mean Response Time _____Seconds

Figure 5. Response Time Determination

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